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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUN 3 0 2005

EnvirOx, LLC 1938 E. Fairchild Street Danville, IL 61382

AGENT: ChemReg International, LLC 1990 Old Bridge Road, Suite 201 Lake Ridge, VA 22192-2383

Attention: Janine Polizzi.

Subject: H<sub>2</sub>Orange, Concentration 117

EPA Registration No. 69268-2

Your Notification Dated June 7, 2005

This will acknowledge receipt of your notification to remove "or more" from the following sentences under the Directions for Use: "... when used as directed as a sanitizer, kills 99.99% from the following..." and "when used as directed as a virucide, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 kills the following viruses in 5 minutes...", submitted under the provisions of FIFRA Section 3(c)(9).

Based on a review of the submitted material, the following comments apply.

The Notification is in compliance with PR Notice 98-10 and is acceptable. This information has been added to your file.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely

Product Manager (33)

Regulatory Management Branch 1 Antimerobials Division (7510C)

CONCURRENCES

SYMBOL

RIPHAME

DATE

EPA Form 1320-1A (1/90)

Pristed on Recycled Paper

OFFICIAL FILE COPY

#### DEODORIZING

For general deodorizing, use 2 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 per 126 parts of cold tap water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 118 (10 oz / gallon) parts of cold tap water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold stains, and surfaces in musty closets.

#### CLEANING SOLUTION DILUTIONS & APPLICATIONS

LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)
Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)

General wipe down cleaner Mopping solution for Bathroom and Kitchen floors General carpet spot remover

HEAVY DUTY (10 Oz / gal) RED (bottle or label) Bathroom, shower room, tile & grout cleaner

Urine and garbage odor eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew stains

SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)

Renovation of tile & grout surfaces
Difficult urine & garbage odor destruction
Scuff marks and stubborn stains
Cleans heavy mold & mildew stains

OPTIONAL MARKETING STATEMENTS: (one or more or none of the following may appear)

New! (for first 6 months only)

Registered for control of [Hepatitis B Virus]/[HBV]

Registered to kill [Hepatitis B Virus]/[HBV]

Starburst design as graphic which may contain the optional marketing statement(s): eg,



ESL: 1/13/2005

Notif: 4/18/2005, 4/25/2005, 6/07/2005

4

# **DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

H<sub>2</sub>Orange<sub>2</sub> Concentrate 117, when used as directed as a sanitizer, kills 99.99% or more of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruinosa, Streptococcus faecalis, and Escherichia coli. When used as directed as a virucide, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 kills the following viruses in 5 minutes or more at room temperature (20+/-1° C): Herpes simplex virus Type 2, Influenza A2/Japan, HBV (Hepatitis B Virus) and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of cold tap water.

CLEANING AND SANITIZING: Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace mop-bucket solution daily.

TO USE AS A SANITIZER AND VIRUCIDE IN BATHROOMS: Add 10 oz. of product concentrate per gallon of cold tap water for sinks, faucets, counters, urinals, toilets (non-water covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace mop-bucket solution daily. Follow instructions for inanimate, hard, non-porous surfaces.

TO USE AS A SANITIZER AND VIRUCIDE ON INANIMATE, HARD, NON-POROUS SURFACES: Add 10 ounces of product concentrate per gallon of cold tap water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer with a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace mop-bucket solution daily.

HIV-1 and HBV: To kill HIV-1 in 5 minutes at room temperature (20-25°C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 per 127 parts of cold tap water). To kill HBV in 5 minutes at room temperature (20-25°C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 10 oz / gallon. For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS) or HBV (Hepatitis B Virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV (HEPATITIS B VIRUS) AND HIV-I (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label. For HBV, use concentration of 10 oz/gallon and leave surfaces wet for 5 minutes.

Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

# DEODORIZING

For general deodorizing, use 2 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 per 126 parts of cold tap water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 118 (10 oz / gallon) parts of cold tap water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold stains, and surfaces in musty closets.

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Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

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General wipe down cleaner Mopping solution for Bathroom and Kitchen floors General carpet spot remover

# HEAVY DUTY (10 Oz / gal) RED (bottle or label)

Bathroom, shower room, tile & grout cleaner
Urine and garbage odor eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew stains

# SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)

Renovation of tile & grout surfaces
Difficult urine & garbage odor destruction
Scuff marks and stubborn stains
Cleans heavy mold & mildew stains

OPTIONAL MARKETING STATEMENTS: (one or more or none of the following may appear)

New! (for first 6 months only)

Registered for control of [Hepatitis B Virus]/[HBV]

Registered to kill [Hepatitis B Virus]/[HBV]

Starburst design as graphic which may contain the optional marketing statement(s): eg,



ESU: 1/13/2005

Notif: 4/18/2005, 4/25/2005, 6/07/2005

APR 2 & MINS

Connie Welch Agent for Envirox, LLC c/o ChemReg International 1990 Old Bridge Road, Suite 201 Lake Ridge, VA 22192-2383

Subject:

H2Orange2 Concentrate 117

EPA Reg. No. 69268-2 Notification Dated 4/18/05

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to change "Replace solution daily" with "Replace mop-bucket solution daily", to provide an additional container size of one quart, and to revise the "First Aid" statements as required by PR Notice 2001-1, is acceptable.

Your notification has been made a part of the permanent records for this file.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,

Marshall Spindell, &

Product Manager Team 33,

Regulatory Management Branch I Antimicrobials Division (7510C)



#### 1990 OLD BRIDGE ROAD, SUITE 201 LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-2717 MAIN: 703-492-0445 Fux:

703-492-0668

E-MAIL:

polizzi@chemreg.com WEB SITES: www.chemreg.com www.pesticide.net

JANINE M. POLIZZI

April 18, 2005

Document Processing Desk (NOTIF) U.S. Environmental Protection Agency (7504C) Office of Pesticide Programs Room 266A, Crystal Mail 2 1801 South Bell Street Arlington, VA 22202-4501

Marshall Swindell (PM 33) Attn:

H-ORANGE: CONCENTRATE 117, EPA Reg. No. 69268-2

Notification per PR 98-10 for Other Revisions

#### Dear Marshall:

On behalf of our client, EnvirOx, LLC, we are submitting the enclosed notification under PR 98-10 (Section II.N) for the above product. For product stewardship purposes, we are clarifying the statement, "Replace solution daily "with "Replace mop-backet solution daily".

in addition, we are notifying that this product will be sold in an additional container size-one quart. The labeling statements are unaffected by this change.

Finally, we have revised the First Aid Statement per PR Notice 2001-1.

Euclosed please find EPA Form 8570-1, as well as one (1) copy of the label with the revisions highlighted. Please contact me by phone or email if there are any questions or concerns about this notification.

Sincerely,

Janine Polizzi

ce: EnvirOx, LLC

CONSULTANTS TO SUCCESS®

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.

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Janine Polizzi <polizzi@chemreg.com> 05/04/2005 03:07 PM To Tony Kish/DC/USEPA/US@EPA

cc "Connie B. Welch" <welch@chemreg.com>

bcc

Subject H2ORANGE2 CONCENTRATE 117, EPA Reg. No. 69268-2

# Dear Tony:

Per your request, we have updated the application and cover letter for the notification for H<sub>1</sub> ORANGE<sub>2</sub> CONCENTRATE 117, EPA Reg. No. 69268-2. The attached cover letter and application replace those that were emailed on April 25, 2005.

Thank you for your help and for revising the acceptance letter to include changes to the First Aid Statement.

<<20050404.to EPA.Cover and Application EPA Reg. No. 69268-2.Notif.Rev. First Aid, new size, replace soln daily.pdf>>
Best wishes,

# -- Janine

Janine Polizzi, M.S. ChemReg International, LLC 1990 Old Bridge Road, Suite 201 Lake Ridge, VA 22192

Phone: 703-492-2717 Fax: 703-492-0668

Email: polizzi@chemreg.com <mailto:polizzi@chemreg.com>

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20050404 to EPA Cover and Application EPA Reg. No. 69268-2 Notif. Rev. First Aid, new size, replace soln daily pdf



Janine Polizzi <polizzi@chemreg.com> 04/25/2005 04:10 PM To Tony Kish/DC/USEPA/US@EPA

CC

pcc

Subject H2ORANGE2 CONCENTRATE 117, EPA Reg. No. 69268-2

Dear Tony:

Per your request, we have updated the application, cover letter and label for the notification for H ORANGE, CONCENTRATE 117, EPA Reg. No. 69268-2. The attached documents replace those that were hand-delivered on April 18, 2005.

Thank you for assisting us with this application.

Please contact me if you have any questions.

<<20050425, Label, EPA Reg. No. 69268-2. Notificiarity replace solution and rev. first aid.pdf>>

<<20050425.Cover and Application.EPA Reg.No. 69268-2.Notif.Replace Soln and Rev First Aid.pdf>>

Best regards,

-- Janine

Janine Polizzi, M.S. ChemReg International, LLC 1990 Old Bridge Road, Suite 201 Lake Ridge, VA 22192

Phone: 703-492-2717 Fax: 703-492-0668

Email: polizzi@chemreg.com <mailto:polizzi@chemreg.com>

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20050425 Label EPA Reg.No. 69268-2 Notificiality replace solution and rev. first aid pdf

20050425. Cover and Application EPA Reg No. 69268-2. Notif. Replace Soln and Rev First Aid.pdf

# H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES

**ACTIVE INGREDIENT** 

Hydrogen peroxide

3.95%

OTHER INGREDIENTS

96.05%

TOTAL

100.00%

# KEEP OUT OF REACH OF CHILDREN

# **CAUTION**

# SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 69268-2

EPA Est. No. 69268-IL-001

Envirox, LLC 1938 E. Fairchild St., Danville, IL 61832

# **NET CONTENTS:**

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (!) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

# PRECAUTIONARY STATEMENTS – HAZARDS TO HUMAN AND DOMESTIC ANIMALS

CAUTION. Causes moderate eye damage. Harmful if swallowed, absorbed through the skin, or inhaled. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling.

After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.

FIRST AID

If in eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact tenses; if present, after the first 5 minutes, then, continue rinsing eye (Call a poison control center or doctor for treatment advice)

If on skin of clothing: Take off contaminated clothing. Runse skin immediately with plenty of water for 15 to

20 minutes (Call a poison control center of doctor for treatment advice)
If swallowed: Call a poison control center of doctor immediately, for treatment advices Have person sip a glass of water if able to swallow. Do not induce yomiting unless told to do so by a poison control center of doctor. Do not give anything by mouth to an unconscious person.

If inhaled: Move person to freshrair: If person is not breathing, call 9(1) or an ambulance, the highest artificial

If inhaled: Move person to freshlair: It person is not breathing; call 9) It or an ambulance, then give artificial respiration; preferably mouth to mouth, it possible: Call a poison control center or doctor for further treatment advice.

Note to Physician: Probable mucosal damage may contraindicate the use of gastric lavage

#### STORAGE AND DISPOSAL

IN CASE OF SPILL: Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

STORAGE: Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL**: Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Completely empty container. Do not reuse empty containers. If in plastic bag with original box discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke or if in plastic bottles, triple rinse or equivalent and recycle.

Questions? Call 1-800-281-9604

#### DIRECTIONS FOR USE

It is violation of Federal law to use this product in a manner inconsistent with its labeling,

H<sub>2</sub>Orange<sub>2</sub> Concentrate 117, when used as directed as a sanitizer, kills 99.99% or more of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruinosa, Streptococcus faecalis, and Escherichia coli. When used as directed as a virucide, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 kills the following viruses in 5 minutes or more at room temperature (20+/-1° C): Herpes simplex virus Type 2, Influenza A2/Japan, HBV (Hepatitis B Virus) and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of cold tap water.

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HIV-1 and HBV: To kill HIV-1 in 5 minutes at room temperature (20-25°C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 per 127 parts of cold tap water). To kill HBV in 5 minutes at room temperature (20-25°C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 10 oz / gallon. For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS) or HBV (Hepatitis 8 Virus).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HBV (HEPATITIS B VIRUS) AND HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings.

Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label. For HBV, use concentration of 10 oz/gallon and leave surfaces wet for 5 minutes.

Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

#### DEODORIZING

For general deodorizing, use 2 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 per 126 parts of cold tap water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 118 (10 oz / gallon) parts of cold tap water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold stains, and surfaces in musty closets.

# **CLEANING SOLUTION DILUTIONS & APPLICATIONS**

LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)
Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)

General wipe down cleaner Mopping solution for Bathroom and Kitchen floors General carpet spot remover

HEAVY DUTY (10 Oz / gal) RED (bottle or label)

Bathroom, shower room, tile & grout cleaner
Urine and garbage odor eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew stains

SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)

Renovation of tile & grout surfaces
Difficult urine & garbage odor destruction
Scuff marks and stubborn stains
Cleans heavy mold & mildew stains

OPTIONAL MARKETING STATEMENTS: (one or more or none of the following may appear)
New! (for first 6 months only)
Registered for control of [Hepatitis B Virus]/[HBV]
Registered to kill [Hepatitis B Virus]/[HBV]
Starburst design as graphic which may contain the optional marketing statement(s): eg,



ESL: 1/13/2005

Notific Clarification of statement 4/1/8/2005 First Aid 4/25/2005

SUBMISSION BAR CODE # 76 3349 REVIEWER KLeary- Munk CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS FILE SYMBOL/REG NO. 69268-2 PM 33 ACTION CODE A 57 DESCRIPTOR Amandment FQPA NFQPA [ ] CHILD RESISTANT PACKAGING: [ ] REQUIRED [ ] NOT REQUIRED REGISTRATION TYPE: [ ] CONDITIONAL [ ] UNCONDITIONAL [ ] RESTRICTED USE DATE ON APPLICATION EPA RECEIVE DATE PM RECEIVE DATE 07/06/04 07/06/04 07/07/04 METHOD OF SUPPORT FORMULATORS EXEMPTION [ ] CITE-ALL [ ] SELECTIVE [ ] SUBMITTED [ ] NOT SUBMITTED NOT SUBMITTED [ ] N/A . [ ] E/A DUB DATA REVIEW(S) REQUESTED DATE PACK # Sent DATE RETURNED CHEMISTRY\_\_\_\_\_] [\_\_\_\_\_] [\_\_\_\_\_] [\_\_\_\_\_\_] RASSB TOX. \_\_\_\_\_][\_\_\_\_\_\_][\_\_\_\_\_\_\_\_] ENVIRON. PATE \_\_\_\_\_][\_\_\_\_][\_\_\_\_][\_\_\_\_] PISH/WILDLIFE\_\_\_\_\_\_][\_\_\_\_\_][\_\_\_\_\_][\_\_\_\_\_] OTHER:\_\_\_\_\_\_][\_\_\_\_][\_\_\_\_][\_\_\_\_]

DECISION PKG. NO. 345946 SUBM. DUB DATE 01-23-05

RESPONSE DATE 1/13/05 24

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



WASHINGTON, D.C. 20460

JAN 13 2005

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Elizabeth Anne Brown Regulatory Agent for, c/o Envirox LLC 1990 Old Bridge Road, Suite 201 Lake ridge, VA 22192-2383

Subject: H<sub>2</sub>Orange, Concentrate 117

EPA Registration Number 69268-2

Your Submission Dated November 19th, 2004 EPA Received Dated November 19th, 2004

The amendment application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act(FIFRA), as amended, to add the Hepatitis B virus to the product labeling, is acceptable.

# **EFFICACY**

The submitted data (MRID Nos. 463095-01 and 463095-2) support the use of the product, H,Orange, Concentrate 117, as a virucide against the Hepatitis B virus on hard, non-porous surfaces for a contact time of 5 minutes in the presence of organic soil at a 1:12.8 dilution at room temperature.

# **LABELING**

The proposed label claims that the product, H2orange2 Concentrate 117, is an effective virucide against HBV(Hepatitis B virus) in 5 minutes at room temperature at a concentration of 10 oz. product per gallon of cold temperature on inanimate, hard, non-porous surfaces. This claim is acceptable.

On page 2, under the "First Aid" instructions, change the phrase, "gentle stream on water" to read "gentle stream of water."

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely.

Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7510C)



# 1990 OLD BRIDGE ROAD, SUITE 201 LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905

Main: 703-492-0445

Fax:

703-492-0668

E-MAIL:

brown@chemreg.com

WEB SITES: www.chemreg.com

www.pesticide.net

ELIZABETH A. BROWN, PH.D.

November 19, 2003

Mr. Marshall Swindell
US Environmental Protection Agency
Office of Pesticide Programs
Antimicrobial Division
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Dear Marshall:

On behalf of our client, Envirox LLC, thank you for taking the time today to discuss with me several questions pertaining to the requirements and approaches for adding control of Hepatitis-B Virus to the labels for the 3 products registered by Envirox. This memo is to confirm our conversation and agreements.

The three products already registered are as follow:

- 1. H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112 (EPA Reg. No. 69268-1). Most recent EPA approval March 14, 2002. Registered as Sanitizer (non-food contact surfaces), Virucide. Currently labeled virucidal uses are against HIV-1, Herpes simplex, virus Type 2, Influenza A<sub>2</sub>/Japan.
- H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 (EPA Reg. No. 69268-2). Most recent EPA approval March 14, 2002. Registered as Sanitizer (non-food contact surfaces), Virucide. Currently labeled virucidal uses are against HIV-1, Herpes simplex virus Type 2, Influenza A<sub>2</sub>/Japan.
- 3. H<sub>2</sub>Orange<sub>2</sub> 120 Ready to Use (EPA Reg. No. 69268-3). Most recent EPA approval March 14, 2002. Registered as Sanitizer (non-food contact surfaces), Virucide. Currently labeled virucidal uses are against HIV-1, Influenza A<sub>2</sub>/Japan.

In prior discussions, you raised as a potential concern whether Agency policy would allow virucidal claims with a sanitizer level registration or whether virucidal claims only could accompany a disinfectant level claim. The Agency clearly has a policy that a product can be registered as a virucide without first being registered as a disinfectant. That policy is defined in

# CONSULTANTS TO SUCCESS<sup>SM</sup>

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.



Letter to M. Swindell, Nov. 19, 2003, page 2

Draft 40 CFR 156, as available on the EPA/OPP/AD website. In 156.441, virucide is separately defined from disinfectants and all other types of activity. Under 156.448 (2), it clearly is stated that a product which meets the performance standard as a virucide "but is not a disinfectant" may be registered with the appropriate limited claims. The already-registered virucidal uses of the Envirox products without disinfectant claims are clearly in line with that policy. Further, DIS/TSS-7, Efficacy Data Requirements for Virucides and the performance standards in the above 156.441 and 448 do not specify any requirement for a virucide to be a disinfectant against bacteria.

Under EPA policy and testing guidelines, the term "disinfectant" is based solely on a level of efficacy against bacteria, while "virucide" is based solely on testing against viruses. The terms are not interchangeable. A product registered as a disinfectant cannot claim virucidal activity unless all required testing for virucidal activity has been conducted and the product meets all pertinent performance standards. And there is nothing in the regulations which requires a virucidal claim to be predicated upon a disinfectant claim against bacteria. In fact, FIFRA Section 4(i)(4)(c) includes the following wording, which is not contradicted elsewhere in that law (emphasis added):

"For purposes of this subparagraph, the term "antimicrobial active ingredient" means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are--

- (i) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surface or in water or air;
- (ii) bacteriostats intended to inhibit the growth of bacteria in the presence of moisture;
- (iii) disinfectants intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or inanimate objects;
- (iv) sterilizers intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces; or
- (v) fungicides or fungistats."

Thus, a pesticide product clearly can be a virucide without first having been determined to be a disinfectant.

In our discussions, you agreed that the above position is correct and that Envirox could add claims against Hepatitis-B virus to the 3 registered product labels if acceptable performance data are submitted.

You then confirmed that the appropriate testing protocol to follow to determine the efficacy against and to support addition of the claim to the labels for Hepatitis-B virus is the *in vitro* (test tube) duck assay (65 FR 51828-51830, August 25, 2000) and as appears on the EPA/OPP/AD website under Registration Policy Documents.



Letter to M. Swindell, Nov. 19, 2003, page 3

Thank you again for taking the time to discuss these issues with me and for confirming the appropriate approach. Once Envirox has developed the appropriate data, the company will submit for label amendments under the above agreements. If I have misunderstood or omitted anything from our discussions, please let me know immediately.

Regards,

Elizabeth Anne Brown

cc: Envirox, LLC

Decision Seq. 345946	Action Code A57 AMEHD	MEIT HOIL FAST TRACK: 180		Decision Status
FFS Start Date: 27-Jul-2	004	FES Original Decisio		Tracking
Due Date 73-Jan	2005.	FFS EUP Decisio		Creete Resubmission
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Mujidel

1/13/05

Keep in File

DP #: (311285)

Decision #: 345946

# DATA PACKAGE BEAN SHEET

Date: 10-Dec-2004 Page 1 of 3

# \* \* \* Registration Information \* \* \*

Registration:	69268-2 - H2ORANG	E2 CONCENTRATE 117	_,	<del></del>	
Company:	69268 - ENVIROX, LI	.c			
Risk Manager:	RM 33 - Marshall Swi	ndell - (703) 308-6341 Room	# CM-2 308H		
Risk Manager Reviewer:	Karen Leavy KLEAV	Y			
Sent Date:		Calculated Due D	ate: 23-Jan-2005	Edited Due Da	te:
Type of Registration:	Product Registration	Section 3			
Action Desc:	(A57) AMENDMENT:	NON-FAST TRACK;			
Ingredients:	000595, Hydrogen pe	roxide(3.95%)			
	Yes ♠ No 000595, Hydrogen pe	rovida	ent: 06-Dec-2004	Due Ba	ok:
DP Title:					
CSF Included:		Label included: • Yes		OP #:	
Assigned To	<u>.</u>	Date In	Date Out		
Organization: AD / P	SB	07-Dec-2004		Administrative Due Date	e: 04-Jun-2005
Team Name: <u>EET</u>		07-Dec-2004	10-Dec-2004	Negotialed Due Date	e:
viewer Name: Wawz	ysko, Marcie	07-Dec-2004	10-Dec-2004	Projected Completion Date	e:
Contractor Name:			_		
viewer Name: Wawz			10-Dec-2004	Projected Completion Dat	<b>e</b> :

# \* \* \* Studies Sent for Review \* \* \*

Printed on Page 2

# \* \* \* Additional Data Package for this Decision \* \* \*

Printed on Page 3

# \* \* \* Data Package Instructions \* \* \*

Please review the efficacy data supporting the proposed labeling claims (Hepatilis B virus). This data was routed to efficacy on September 6th, 2004; however, it was returned and closed out without being reviewed. This data is boing submitted to efficacy again. PRIA, Action Code A57, Admin due date 01/23/2005, 5TT due date 01/15/2005.

DP#: (3112	285)	* * * Studies Sent for Review * * *	Decision#: (345946)
MRID		Citation Reference	Guideline
46309501	Ramm, K. (2004) Virucidal Environmental Surfaces Ui H2Orange2 Concentrate 1	Efficacy of a Disinfectant for Use on Inanimate tilizing Duck Hepatitis B Virus: Final Study Report: 17. Project Number: A02079, E0X01030804/DHBV/1.	
46309502	Surfaces Duck Hepatitis B	Efficacy of a Disinfectant for Use on Inanimate Environmenta Confirmatory Assay: Final Study Report: H2Orange2 Number: A02078, EOX01030804/DHBV/2. Unpublished	al

Page 3

DP#: (3112	(85)	* * * Additional Data Package for this Decision * * *	Decision#: (345946)
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305482	AD / RMB1	15-Jul-2004 23-Dec-2004 ( Yes ( No	● Yes ○ No ● Yes ○ No
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Bean Court: 1 Plate Package file:    Parent DP #   Date Reckage in your	Been Sheet
Linstructions Please review the efficacy data supporting the proposed labeling claims (Hepatitis B virus). This data was routed to efficacy on September 8th, 2004; however, it was returned and closed out without being reviewed. This data is being submitted to efficacy again. PRIA, Action Code A57, Admin due date 01/23/2005, ETT due date 01/15/2005.	
Sent to Sent from Copp Dates MRIDS Sub-DR Lo DP Ingredients In DPI Contract  Under Package Comments (Waive: Documentation)	Receipts
Elas Cara Santa Santa District Data Commentary 2. Commenta	
Primary and confirmatory studies against DBHV were acceptable under Agency guidelines. Product is a sanitizer with virucidal claims, this has been previously approved.	
Viewing Record Fol 1	TE PERMIT

FRONT PANEL - /ENVIROX 117

MASTER LABEL

03-11-02

(logo)

H<sub>2</sub>ORANGE, CONCENTRATE 117

OXIDIZING MULTI PURPOSE CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES

ACTIVE INGREDIENT
Hydrogen peroxide

3.95%

**OTHER INGREDIENTS** 

96.05%

TOTAL

100.00 %

KEEP OUT OF REACH OF CHILDREN

# CAUTION

PRECAUTIONARY STATEMENTS

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 69268-2 EPA Est. No. 69268-IL-001

> ENVIROX, LLC 1938 E. FAIRCHILD ST DANVILLE, IL 61832

ACCEPTED

MAR I 4 2002

Under the Federal Insectición, Fungición, and Rodentición Act as amended, for the postición, registered under

EPA Reg. Ho 6 9268-2

NET CONTENTS: 5 gal (640 oz);1 gal (128 oz, 3784 ml); 32 oz(946 ml)

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical devices prior to sterilization or high level disinfection.

03-11-02 EnvirOx 800-281-9604

# PRECAUTIONARY STATEMENTS

# HAZARDS TO HUMAN AND DOMESTIC ANIMALS

Caution. Causes moderate eye damage. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Avoid contamination of food.

After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.

## FIRST AID

IF IN EYES: Hold eye open. Rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then, continue rinsing eye. Call a polson control center or doctor for treatment advice.

IF ON SXIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vemiting unless told to do so by a poison control center or doctor. Oo not give anything by mouth to an unconscious person.

IF INHALED: Move victim to fresh air. If not breathing, call 911 or an ambulance, then, give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control venter or doctor for further treatment advice.

# STORAGE AND DISPOSAL

IN CASE OF SPILL: Clean up immediately. To clean up spill, flush area with large quantity of water.

**STORAGE**: Do not contaminate water, food, and or feed by storage. Store below 95°. Keep concentrate away from incompatible materials.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by disposal.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Rinse and recycle or dispose of in trash.

# **DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

H<sub>2</sub>Orange<sub>2</sub> Concentrate 117, when used as directed as a sanitizer, kills 99.99% of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruinosa, Streptococcus teecalis, and Escherichia coli. When used as directed as a virucide, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 kills the following viruses in 5 minutes at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A<sub>2</sub>Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

ACCEPTED

MAR 1 4 2002

Under the Federal Insecticide, Fungicide, and Podenticide Act as amended, for the pasticide, registered under EPA Reg. No. 6 9 2 6 8 - 2

<u>Cleaning:</u> Using appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces: Add 10 curces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer using a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

To use as a sanitizer and virucide in bathrooms: Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals (non-water covered surfaces), toilets (non-water covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily. Follow instructions for inanimate, hard, non-porous surfaces.

<u>HIV-1:</u> To kill HIV-1 in 5 minutes at room temperature (20-25° C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

<u>Personal Protection:</u> Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned form surfaces and objects before application of diluted product using the Heavy Duty or Super. Duty Cleaning Solution.

Contact time: While the HTV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

<u>Infectious Materials Disposal</u>: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

# Deodorizing

For general deodorizing, use 2 part H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-lieostomy dressing and bag changes, and other spills such as urine or fecal matter, smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

MAR I 4 2002

Under the Federal Insecticide, Fungicide, and Rodanticide Act as amended, for the pesticide, registered under EPA Risg. No. 6 9 2 6 8 - 2

03-11-02 EnvirOx 800-281-9604

# **CLEANING SOLUTION DILUTIONS & APPLICATIONS**

LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)
Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)
General wipe down cleaner
Mopping solution for Bathroom and Kitchen floors
General carpet spot remover

HEAVY DUTY (10 Oz / gal) RED (bottle or label)
Bathroom, shower room, tile & grout cleaner
Urine and garbage odor eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew

SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)
Renovation of tile & grout surfaces
Difficult urine & garbage odor destruction
Scuff marks and stubborn stains
Cleans heavy mold & mildew

# DIRECTIONS FOR CONSUMER LABEL - CLEANING DILUTIONS

# **CLEANING APPLICATIONS**

# Bathroom surfaces

USE HEAVY\_DUTY DILUTION (10 oz/gat). Spray sink, faucets, counter, toilet, (and floor around toilet), tub and shower liberally. Let sit for 5 min. then wipe or scrub clean. No rinse is required. Use as daily shower spray to prevent soil buildup. Spray surfaces after shower and let air dry.

# Kitchen surfaces

USE HEAVY DUTY DILUTION (10 oz/gal). Spray and wipe clean. For heavy soils on hood and stovetops, spray and let sit a few minutes than scrub or wipe clean. For oddr control in garbage containers, spray tightly before inserting plastic tiner.

## Carpet stains

USE CARPET SPOTTER DILUTION (2 oz/gal). Before cleaning, test a hidden section for color fastness. Remove gross soil, then soak spot and let sit for 5 to 10 min. Biot spot with a clean, soft cloth. Repeat as necessary. For petroleum-based stains use Super-Duty Dilution(24-48 oz/gal) and rinse with clean water.

#### Glass surfaces

USE LIGHT DUTY DILUTION (1 oz/gal). Spray surface and wipe clean. It is not neces sary to polish the surface dry.

# Laundry pre-spray

USE SUPER DUTY DILUTION (24-48 oz/gat). Test delicate fabrics in hidden area for color fastness. Soak spot and let sit for at least 15 min., than launder or scrub and rinse as usual.

#### Tough soils

USE SUPER DUTY DILUTION 24-48 oz/gal). Spray soil, let six a few minutes, then scrub or wipe clean. Use for oil and grease, bugs and tar on automobiles, dried food residue and pet soils.

ACCEPTED

MAR 1 4 2002

Under the Federal Insecticitie, Fungicide, and Rodernbolde Act as amended, for the pestic hie, registered under EPA Reg. No. 69164-2

4

# Elizabeth Brown

From:

Elizabeth Brown

Sent:

Thursday, July 15, 2004 1:45 PM

To:

'leavy.karen@epa.gov'

Subject:

EPA Reg. No. 69268-2

# Karen:

On behalf of our client, Envirox LLC, and as requested in your phone call of Tuesday, July 13, attached please find as pdf files the following items:

- Data matrix (Agency File and Public Use Copies) updated to show the assigned MRIDs for the data submitted in support of the pending amendment for this product
- Certification with Respect to Citation of Data

Please confirm receipt of these items, and please don't hesitate to let me know if you have any questions or need anything further.

Regards, Elizabeth







20040713.Data

data citatio...

matrix Concentra... matrix Concentra...

Elizabeth Anne Brown, Ph.D. Director, Scientific & Regulatory Affairs ChémReg International 1990 Old Bridge Road, Suite 201 Lake Ridge, VA 22192

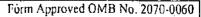
Phone: 703-492-7905 Fax: 703-492-0668

Email: brown@chemreg.com

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11/19/2004

Karen. D'ue not yet had confunction of receipt from you, so here's a hard copy. Elizabeth





# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

# DATA MATRIX

Date: July 13, 2004		EPA Reg No./ File Symbol 69268-2	Page 1 of 1
Applicant's/Registrant's Name and Address:	Envirox, LLC 1938 E. Fairchild Street P.O. Box 2327	Product: H2Orange2 Concentrate 117	<del></del>
•	Danville, IL 61834		

Guideline R	eference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
158.20	61-1 to -3	Product Chemistry	44532001	Envirox, LLC	Own	69268-1
158.20	62-1 to <b>–</b> 3	Product Chemistry	44532001	Envirox, LLC	Own	69268-1
158.20	63-2 to -21	Product Chemistry .	44532001	Envirox, LLC	Own	69268-1
158.135	81-1 to 81-6	Toxicology	44532004	Envirox, LLC	· PL	
158.20	Efficacy	AOAC Sanitizer Test	44532002	Envirox, LLC	Own	69268-I
158.20	Efficacy	HIV Virucidal Test	44532003	Envirox, LLC	Own	69268-1
158.20	Efficacy	Virucidal effectiveness	44560101	·Envirox, LLC	Own -	69268-I
158.20	61-1 to -3	Product Chemistry	44582301	Envirox, LLC	Own	69268-2
158.20	62-1 to -3	Product Chemistry	44582301	Envirox, LLC	Own	69268-2
158.20	63-2 to -21	Product Chemistry	44582301	Envirox, LLC	Own	69268-2
OPPTS 810	.2100	Virucidal efficacy (HBV)	46309501 46309502	Envirox, LLC ·	Own	69268-2

2

Signature	Name and Title	Date
Elizabet and Brown	Elizabeth Anne Brown	7/13/2004
Cusamer axxe 10102040	ChemReg International, Agent for Envirox LLC	<u> </u>



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, U.C. 20460

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# Date: July 13, 2004 EPA Reg No./ File Symbol 69268-2 Applicant's/Registrant's Name and Address: Envirox, LLC 1938 E. Fairchild Street P.O. Box 2327 Danville, IL 61834 Ingredient: Hydrogen Peroxide

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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			Envirox, LLC	Own	69268-2
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			Envirox, LLC	Own	69268-2

1/1

Signature	Name and Title	Date
Ylejaheer die Brown	Elizabeth Anne Brown	7/13/2004
L_/	ChemReg International, Agent for Envirox LLC	

Form Approved OMB No. 2070-0060



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M STREET, S.W. WASHINGTON, D.C. 20460

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	Do not send the completed form to this address.						
H	Certification with Respect to Citation of Data						
	Applicant's/Registrant's Name, Address, and Telephone Number Envirox, LLC 1938 E. Fairchild Street P.O. Box 2327		EPA Registration Number/File Symbol 69268-2				
·H	Danville, IL 61834 217-442-8596						
	Active Ingredient(s) and/or representative test compound(s) Hydrogen peroxide		Date July 14, 2004				
	General Use Pattern(s) (list all those claimed for this product using 40	CFR Part 158)	Product Name H <sub>2</sub> Orange <sub>2</sub> Concentrate 117				
	NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulators Exemption Statement (EPA Form 8570-27)						
	I am responding to a Data-Call-in Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).						
L	SECTION I: METHOD OF DATA SUPPORT (Check one method only)						
	l am using the cite-all method of support, and have included withis form a list of companies sent offers of compensation (the Matrix form should be used for this purpose)		I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).				
Г	SECTION II: GENERAL OFFER TO PAY						
Г	Required if using the cite-all method, or when using the cite-all option under the selective method to satisfy one or more data requirements]						
	,	offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA					
	SECTION III: CERTIFICATION						
I certify that this application for registration, this form for reregistration or this Data-Call-In response is supported by all data submit the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under selective method is indicated in Section 1, this application is supported by all data in the Agency's files that (1) concern the properties or exproduct or an identical or substantially similar product, or one or more of the ingredients in this product, and (2) is a type of data that would be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration identical or similar composition and uses.							
١,	I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have plained the written permission of the original data submitted to cite that study.						
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility from compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation. If any, to be paid for the use of the study.  I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delive accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should, I fail to prodict such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product conformity with FIFRA.  I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.							
				[3	lignature	Date	Typed or Printed Name and Title
					Legende and Brown	7/14/2004	Elizabeth Anné Brown ChemReg International, LLC, Agent for Envirox, LLC
3	PA Form 8570-34 (9-97) Electronic and Paper versions available. Submit on	ly Paner version					



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

# December 10, 2004

# **MEMORANDUM**

Subject:

Efficacy Review for H2Orange2 Concentrate 117, EPA Reg. No. 69268-2;

DP Barcode: D311285

From:

Marcie Wawzysko, Microbiologist Marcieh augysko
Product Science Branch
12/10/04
12/10/04

Thru:

Nancy Whyte, Acting Team Leader

Product Science Branch

Antimicrobials Division (7510C)

Michele E. Wingfield, Chief Product Science Branch

Antimicrobials Division (7510C)

To:

Marshall Swindell PM 33 / Karen Leavy

Regulatory Management Branch I Antimicrobials Division (7510C)

Applicant:

Envirox, LLC

1938 E. Fairchild Street

P.O. Box 2327 Danville, IL 61832

# Formulation from the Label:

Active Ingredient(s)	<u>% by wt.</u>
Hydrogen Peroxide	3.95%
Other ingredients	96.05%
Total	100.00%

# I. BACKGROUND

The product, H<sub>2</sub>Orange<sub>2</sub> 117, is an Agency registered non-food contact sanitizer and virucide for use on hard, non-perous surfaces. The applicant wishes to add claims to the product for Hepatitis B virus, and has submitted data to support this claim. Studies were conducted by ATS Labs, located at 1285 Corporate Center Drive, Suite 110 in Eagan MN 55121.

The data package contained a letter from the applicant's representative to the Agency (dated November 19, 2003), Agency form 8570-4 (Confidential Statement of Formula), the last accepted label (dated March 14, 2002), the proposed label, and two studies (MRIDS 463095-01 and 463095-02) with Statements of No Data Confidentiality and Good Laboratory Practice for both.

#### II. USE DIRECTIONS

The product is designed for use as a non-food contact surface sanitizer and virucide for hard, non-porous surfaces such as sinks, faucets, counters, urinals, toilets, walls, stalls, and floors. The proposed label gives the following instructions for the use of the product as a sanitizer and virucide on inanimate, hard, non-porous surfaces: Add 10 ounces of product concentrate per gallon of cold tap water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer with a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

The proposed label also gives instructions for cleaning and decontaminating against Hepatitis B virus and HIV-1, and for deodorizing. The label also states that "This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that..."

# III. AGENCY STANDARDS FOR PROPOSED CLAIMS

# Virucides

The effectiveness of virucides must be tested using virological techniques that simulate the conditions under which the product is intended for use. For products with intended use on dry, inanimate environmental surfaces, carrier tests that are variations of either the AOAC Use-Dilution Method (for liquid surface disinfectants) or the AOAC Germicidal Spray Products Test (for surface spray disinfectants) must be used to produce virucidal data. The virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of two different batches of disinfectant must be tested against a recoverable virus titer of at least 10<sup>4</sup> from the test surface (petri dish, glass slide, steel cylinder, etc.) for a specified exposure period at room temperature. The virus must be assayed by an appropriate virological technique testing a minimum of four determinations for each dilution. The protocol for the viral assay must include viral recovery, cytotoxicity controls, and ID-50 values. Test results should be reported as the

reduction of the virus titer by the activity of the germicide (ID-50 of the virus control less the ID-50 of the test system) expressed as  $log_{10}$  and calculated by a statistical method. For virucidal data to be acceptable, the product must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level. The calculated viral titers must be reported with the test results. Separate studies on two batches of product are required for each virus. These Agency standards are presented in DIS/TSS-7.

# Virucides - Novel Virus Protocol Standards

To ensure that a virus protocol has been adequately validated, data should be provided from at least 2 independent laboratories for each product tested (i.e., 2 product lots per laboratory). The validation of a protocol requires the use of a common positive control disinfectant to be tested concurrently with all new products. For the Hepatitis B Virus protocol, the usual control is BTC-835, a quaternary ammonium compound product obtained from Stepan Company. This agent serves as both an intra-laboratory and an inter-laboratory control and is used for analyzing the reproducibility of the efficacy data results for the protocol. These Agency standards are tailored from those presented in the Federal Register, Vol. 65, No. 166, Friday, August 25, 2000.

# IV. SUMMARY OF SUBMITTED STUDIES

1. MRID 463095-01 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces Utilizing Duck Hepatitis B Virus" for H₂Orange₂ 117 by Karen M. Ramm. Study conducted by ATS Labs, Project Number A02079. Study completed June 24, 2004.

This study, under the direction of Karen M. Ramm, was conducted against duck Hepatitis B virus (DHBV16 strain, obtained from Hepadnavirus Testing, Palo Alto, CA) using primary duck hepatocytes (obtained from AppTec Laboratory Services, St. Paul, MN). The study followed ATS Labs protocol number EOX01030804.DHBV.1. Two lots (Lot Nos. 98804 and 98763) were tested. A use dilution of 10oz, product per gallon of sterilized deionized tap water was created (a 3100 ppm dilution). 100% duck serum was present in the viral stock as the organic soil load. Films of the virus were made by spreading 0.2 mL of the viral inoculum over the bottoms of ten sterile glass petri dishes. Viral films were dried for 30 minutes at 20.0°C in 45% relative humidity. For each lot of the product, dried viral films were exposed to 2.0 mL of the use dilution for 5 minutes at 20,0°C. The virus/test agent mixture was immediately passed through Sephadex gel columns to detoxify. The filtrate (considered at 10<sup>-1</sup> dilution) was again passed through a Sephadex column then serially diluted in Leibovitz L-15 medium with 0.1% glucose, 10µM dexamethasone, 10µg/mL insulin, 20mM HEPES, 10µg/mL gentamicin, and 100 units/mL penicillin. Primary duck hepatocytes were inoculated in quadruplicate with 1.0 rnL of each dilution and incubated for viral absorption overnight at 36-38°C and 5-7% CO<sub>2</sub>. Post absorption, 3.0 mL of Leibovitz L-15 medium was added to each cell culture well and cultures were incubated for ten days at 36-38°C and 5-7% CO2. Cultures were then scored for cytotoxicity and cells were fixed with ethanol. Plates were assayed by

indirect immunofluorescence assay. Controls included those for cytotoxicity, neutralization, virus stock titer, and plate recovery. Stepan Company's BTC 835 was used as the data consistency control at two concentrations, 175 and 350 ppm. The  $TCID_{50}$  was calculated by method of Spearman Karber.

Note: Applicant included data from a failed test (conducted May 7, 2004) due to bacterial contamination of the indicator cell cultures.

2. MRID 463095-02 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces: Duck Hepatitis B Confirmatory Assay" for H₂Orange₂ 117 by Mary J. Miller. Study conducted by ATS Labs, Project Number A02078. Study completed May 18, 2004.

This study, under the direction of Mary J. Miller, was conducted against duck Hepatitis B virus (DHBV16 strain, obtained from Hepadnavirus Testing, Palo Alto, CA) using primary duck hepatocytes (obtained from AppTec Laboratory Services, St. Paul, MN). The study followed ATS Labs protocol number EOX01030804.DHBV.2. One lot (Lot No. 98804) was tested. A use dilution of 10oz, product per gallon of sterilized deionized tap water was created (a 3100 ppm dilution). 100% duck serum was present in the viral stock as the organic soil load. Films of the virus were made by spreading 0.2 mL of the viral inoculum over the bottoms of eight sterile glass petri dishes. Viral films were dried for 30 minutes at 20.1°C in 45% relative humidity. Dried viral films were exposed to 2:0 mL of the use dilution for 5 minutes at 20.1°C. The virus/test agent mixture was immediately passed through Sephadex gel columns to detoxify. The filtrate (considered at 101 dilution) was again passed through a Sephadex column then serially diluted in Leibovitz L-15 medium with 0.1% glucose, 10µM dexamethasone, 10µg/mL insulin, 20mM HEPES, 10µg/mL gentamicin, and 100 units/mL penicillin. Primary duck hepatocytes were inoculated in quadruplicate with 1.0 mL of each dilution and incubated for viral absorption overnight at 36-38°C and 2-7% CO<sub>2</sub>. Post absorption, 3.0 mL of Leibovitz L-15 medium was added to each cell culture well and cultures were incubated for ten days at 36-38°C and 2-7% CO2. Cultures were then scored for cytotoxicity and cells were Plates were assayed by indirect immunofluorescence assay. fixed with ethanol. Controls included those for cytotoxicity, neutralization, virus stock titer, and plate recovery. Stepan Company's BTC 835 was used as the data consistency control at two concentrations, 175 and 350 ppm. The TCID<sub>50</sub> was calculated by method of Spearman Karber.

## V. RESULTS

MRID	Organism		Results		Plate
Number			Lot No. 98804	Lot No. 98763	Recovery Control (TCID <sub>so</sub> /mL)
463095-01	Duck Hepatitis B	10 <sup>-2</sup> to 10 <sup>-4</sup> dilutions	Complete inactivation	Complete inactivation	10 <sup>5.0</sup>
	virus	TCID₅₀/mL	≤10 <sup>1.5</sup>	≤10 <sup>1.5</sup>	,0
463095-02	Duck Hepatitis B	10 <sup>-2</sup> to 10 <sup>-4</sup> dilutions	Complete inactivation		10 <sup>5.5</sup>
	virus	TCID₅₀/mL	≤10 <sup>1.5</sup>		.5

## VI. CONCLUSIONS

The submitted data (MRID Nos. 463095-01 and 463095-02) support the use of the product, H<sub>2</sub>Orange<sub>2</sub> 117 as a virucide against the Hepatitis B virus on hard, non-porous surfaces for a contact time of 5 minutes in the presence of organic soil at a 1:12.8 dilution at room temperature. Cytotoxicity was not observed. Complete inactivation (no growth) was indicated in all dilutions tested for virucidal efficacy. Based on the plate recovery control, it appears that a recoverable virus titer of at least 10<sup>4</sup> was achieved. Study controls met the criteria for a valid test.

## VII. RECOMMENDATIONS

- 1. The proposed label claims that the product, H<sub>2</sub>Orange<sub>2</sub> 117, is an effective virucide against HBV (Hepatitis B virus) in 5 minutes at room temperature at a concentration of 10oz, product per gallon of cold tap water on inanimate, hard, non-porous surfaces. This claim is **acceptable**.
- 2. The following change needs to be made to the proposed label on page 2, under First Aid instructions, change "gentle stream o water" to read "gentle stream of water."

	35/2/2		11/25/	/oy
DECISION PKG. NO.	551169	SOBM. I	DUE DATE	-
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DESCRIPTOR Revised	CSFO	FQPA_	× NFQPA	
[ ] CHILD RESISTAN	T FACKAGING:	( ) REQUIR	ed [ ] not reodired	· •
REGISTRATION TYPE: [ ]	CONDITIONAL	ONCONDITION [	AL [ ] RESTRICTED	USE
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Elizabeth Brown, Agent for Envirox c/o Chem Reg International 1990 Old Bridge Road, Suite 201 Lake Ridge, VA 22192

Subject:

H2Orange2 Concentrate 117

EPA Reg. No. 69268-2

Your Notification Dated 10/26/04

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to provide a revised basic Confidential Statement of Formula (CSF), and a new alternate CSF; both dated 10/20/04, is acceptable.

Your notification has been made a part of the permanent records for this file.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,

Marshall Swindell,

Product Manager Team 33,

Regulatory Management Branch I Antimicrobials Division (7510C)

Please read Instructions on reverse before completing form	Form Approved, OMB No. 2070-0060, Approval expires 5-31-98
United States	Registration OPP Identifier Number
SEPA Environmental Protection	Amendment
	X   Other
Washington, DC 20460	
	Pesticide - Section I  2. EPA Product Manager 3. Proposed Classification
Company/Product Number     69268-2	EPA Product Manager     Swindell
4. Company/Product (Name)	PM # None Restricted
H2Orange2 Concentrate 117  5. Name and Address of Applicant (Include ZIP Code)	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)
EnvirOx, LLC	(b)(i), my product is similar or identical in composition and labeling
1938 E. Fairchild Street	to:
Danville, IL 61382	EPA Reg No.
Check if this is a new address	Product Name
<del></del>	ection - II
Amendment - Explain below	Final printed labels in response to
Describeries in consequent Assessed the state of	Acency letter dated
Resubmission in response to Agency letter dated	"Me Too" Application
Notification – Explain below	Other Euplain halaus
Nobilication - Explain Delow	Other – Explain below
Explanation: Use additional page(s) if necessary. (For Section I and	Section II )
Notification of Change in Product Chemistry per PR Notice 98-10, Sec	
	nd EPA regulations at 40 CFR 152.46, and no other changes have been made. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any
	not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this
product may be in violation of FIFRA and I may be subject to enforcement	
Si Si	ection III
Material This Product Will be Packaged in:	
Child-Resistant Packaging Unit Packaging	Water Soluble Packaging 2. Type of Container
Yes	Yes Metal
No No	No Plastic Glass
*Certification must If "Yes" No. per	If "Yes" No. per Paper
be submitted Unit Packaging wgt. container	Package wgt container Other (Specify)
Location of Net Contents Information 4. Size(s) Re	etail Container 5. Location of label directions
Label Container	etail Container 5. Location of label directions On Label
	On Label accompanying product
6. Manner in Which Label is Affixed to Product Lithogra	
Paper ( Stencile	
	ection IV
1. Contact Person (Complete items directly below for identification of it	ndividual to be contacted, if necessary, to process this application.)
Name Title	Telephone No. (Include Area Code)
Elizabeth Anne Brown - ChemRi	eg International, LLC 703-492-7905
Certification	6. Date Application
I certify that the statements I have made on this form and all attachments	
I acknowledge that any knowingly false or misleading statement may be p both under applicable law	unishable by fine or imprisonment or
2. Signature 3. Title	(Stamped)
ChamBi	eg international, LLC
Phiphiel are Brown Authoriz	ed representative for EnvirOx LLC
4. Typed Name 5. Date Elizabeth Anne Brown October	26, 2004
October - Control of C	£U, £VV#
DDL C. DOROLL D. DOLD D.	
EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.	White - EPA File Copy (Original) Yellow - Applicant Copy
•	•••••



## 1990 OLD BRIDGE ROAD, SUITE 201 LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-7905

Main: 703-492-0445

Fax: 703-492-0668

E-MAIL:

brown@chemreg.com

WEB SITES: www.chemreg.com

www.pesticide.net

## ELIZABETH A. BROWN, Ph.D.

October 26, 2004

Contains Confidential Business Information

Document Processing Desk (NOTIF)
U.S. Environmental Protection Agency (7505C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202-4501

Attn: Marshall Swindell (PM 33)

Re:

H2ORANGE2 CONCENTRATE 117, EPA Reg. No. 69268-2

Notification per PR 98-10 for Changes in Product Chemistry

#### Dear Marshall:

On behalf of our client, EnvirOx, LLC, and as discussed with you by phone on Wednesday, October 20, 2004, we are submitting the enclosed notification under PR 98-10 for product chemistry changes for the above product.

The previously accepted CSF was dated 7/29/98 and was accepted by the Agency on 10/23/98. Corrections have been made to the basic confidential statement of formula, and an alternate confidential statement of formula is being submitted at this time. As you specifically directed, these are being submitted as notifications, and I have enclosed an unsigned but detailed commented version of each CSF to clearly identify the corrections and revisions as you requested.

Enclosed please find EPA Form 8570-1, two copies each of the basic and alternate CSF, and one copy each of commented versions of the basic and alternate CSF. Please contact me by phone or email if there are any questions or concerns about this notification. Because of the extent of the corrections, I would appreciate receiving confirmation of the acceptability of this notification by email when the Agency has completed its review.

Sincerely,

Elizabeth Anne Brown

Clipace are Brown

cc: EnvirOx, LLC

## CONSULTANTS TO SUCCESS\*\*

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.

54



## **UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

Carket WASHINGTON, D.C. 20460

16A8.2

July 7, 2004

OFFICE OF PREVENTION, PESTICIDES AND **TOXIC SUBSTANCES** 

## PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-345946

EPA File Symbol or Registration Number: 69268-2 Product Name: H2ORANGE2 CONCENTRATE 117

EPA Receipt Date: 06-Jul-2004 EPA Company Number: 69268 Company Name: ENVIROX, LLC

**ELIZABETH ANNE BROWN ENVIROX, LLC** C/O CHEMREG INTERNATIONAL, LLC 1990 OLD BRIDGE ROAD, SUITE 201 LAKE RIDGE, VA 22192-2383

SUBJECT: Receipt of Amendment Subject to Registration Service Fee

## Dear Registrant:

The Office of Pesticide Programs has received your application for Amendment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: A57

AMENDMENT; NON-FAST TRACK;

Please remit payment in the amount of: \$ 3,000 to:

By USPS: USEPA Washington Finance Center Pesticide Registration Service Fee PO Box 360277 Pittsburgh, PA 15251

By Courier:

U.S. EPA Washington Finance Center Pesticide Registration Service Fee C/O Mellon Client Service Center 500 Ross Street, Room 670 Box 360277 Pittsburgh, PA 15251-6277

Attn: EPA Module Supervisor Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is soley associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how th request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman, at (703) 308-8260.

Sincerely,

Front End Processing Staff

Information Resources and Services Division

# **Fee for Service**

			•
This package includes th	ne following	for Division	
☐ New FFS Action		- □ RD	73
⊠Amendment		⊠ AD	
☐Waiver Request		□ BPPD	
☐Voluntary Payme	ent Request		~~ ~~
Receipt Nos S- 763	3 349		
Product/Risk Manager	: Pm 33		
EPA File Symbol/Reg	No. 69268	7-2	
Pin-Punch Date:	7/6/04		- Exercise
☐ This item is NOT sul	bject to FFS a	action.	
Action Code: A 57	Amo	ount Due: \$ <u>3</u> 0	000
Voluntary Payment Re	duction Amou	<u>int:</u>	
□ 0% □ 40% □ 50% □ 20% □ 60%	¹□ 90% □ 100%	Original Decision #:	
☐ 25% ☐ 70% ☐ 30% ☐ 75%	□ Other I	υ	_
Reviewer: Lantz Not	ple Date	: 7/7/04	
Remarks:	# PC D. L.		

DP #: (305482)

Decision #: 345946

## **DATA PACKAGE BEAN SHEET**

Date: 15-Jul-2004 Page 1 of 1

## \* \* \* Registration Information \* \* \*

Registration:	69268-2 - H2ORANGE2 CO	NCENTRATE 117			
Company:	69268 - ENV!ROX, LLC	·			
Risk Manager:	RM 33 - Marshall Swindell -	(703) 308-6341 Room#	CM-2 308H		
Risk Manager Reviewer.	Karen_Leavy KLEAVY			·	
Sent Date:		Calculated Due Da	te: 23-Jan-2005	Edited Due Date:	
Type of Registration:	Product Registration - Section	on 3			
Action Desc:	(A57) AMENDMENT; NON-F	AST TRACK;		<del></del>	
Ingredients:	000595, Hydrogen peroxidel	3.95%)			
$\overline{}$	***D	ata Package in		<del></del>	
Expedite:	○ Yes   ● No	Date Se	nt: 15-Jul-2004	Due Back:	
OP Ingredient:	000595, Hydrogen peroxide			<del></del>	
DP Title:					
	_	el included:  Yes		DP#:	
Assigned To	<u>o</u>	Date In	Date Out		
Organization: AD / P	SB	<u> </u>		Administrative Due Date:	11-Jan-2005
Team Name: EET			. <del></del>	Negotiated Due Date:	
				Projected Completion Date:	

\* \* \* Studies Sent for Review \* \* \*

No Studies

\* \* \* Additional Data Package for this Decision \* \* \*

No Additional Data Packages

\* \* \* Data Package Instructions \* \* \*

PLEASE REVIEW THE EFFICACY DATA SUPPORTING THE PROPOSED LABELING CLAIM (HEPATITIS B VIRUS).
FEE FOR SERVICE, ACTION CODE A57, ADMIN DUE DATE 01-23-2005, ETT DUE DATE, 12-23-2004.

## Environmental Protection Agency

Office of Pesticide Programs (7505C) Washington, DC 20460

## Notice of Supplemental Distribution of a Registered Pesticide Product

### Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product Distributor Company Number 73835 69268-2 Note: Do not submit distributor product labels Name of Registered Product (basic product name accepted by EPA) Distributor Product Name 1. H2Orange2 Concentrate H2Orange2 Concentrate 117 117 for Manual Dilution. (Manual Dilution) H2Orange 2 Concentrate 117 for Name and Address of Distributor (Type: include ZIP code) Manual Dilutions. 3. H2Orange2 Concentrate 117 for Manual Dilution Performance Food Group 12500 Westcreek Parkway Only Bichmond, VA. 23220

## → Read All Conditions Before Signing

- 1. The distributor product must have the same composition as the basic product.
- 2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product.
- The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
- The product must remain in the manufacturer's unbroken container.
- The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
- 6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for ... ","distributed by ... "; or "sold by ... " to show that the name is not that of the manufacturer.
- 7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

## Distributor

We intend to market our product under the Distributor Product Name specified above, subject to the conditions specified on the

Registrant

I agree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the condition's specified on this ° 🕈

Signifure and Title of Registrant

Date

EPA Form 8570-5 (Rev. 8-94) Previous aditions are obs U.S. GPO: 1998-432-472/81004

White - EPA

United States

## **SEPA**

## **Environmental Protection Agency**

Office of Posticide Programs (7505C)

42 62-2-

Washington, DC 20460

## Notice of Supplemental Distribution of a Registered Pesticide Product

#### Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrant has a potential distributor who does not have a company number assigned, she/he should have the distributor apply, on letterhead stationery, to the Registration Division to have a number assigned prior to submitting this form to the agency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product Distributor Company Number 73835 69268-2 Note: Do not submit distributor product labels Distributor Product Name 1. H2Orange2 Concen-Name of Registered Product (basic product name accepted by EPA) H2Orange2 Concentrate 117 trate 117 for Manual Dilution. (Manual Dilution) . -2. H2Orange2 Concentrate 117 for-Name and Address of Distributor (Type; include 2IP code) Manual and Dispenser Dilutions. Performance Food Group 12500 Westcreek Parkway Richmond, VA 23220

## Read All Conditions Before Signing

- 1. The distributor product must have the same composition as the basic product.
- The distributor product must be manufactured and packaged by the same person who manufactures and packages
  the registered basic product.
- 3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary.
- 4. The product must remain in the manufacturer's unbroken container.
- The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number.
- 6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", "distributed by:.."; or "sold by..." to show that the name is not that of the manufacturer.
- 7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product.

### Distributor

We inlend to market our product under the Distributor Product Name specified above, subject to the conditions specified on this Notice:

Signature and Title of Distributor

(algory maragen 6/08/03

Registrant

Lagree that the distributor named above may distribute and sell the Distributor Product specified above, subject to the conditions specified on this Notice.

Signature and Title of Registrations

The Delecea Hellinger April P

6/6/03

EPA Form 8570-5 (Rev. 8-94) Previous editions are obsolete.

'U.S. GPO: 1998-432-472/81004

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

JUN 1 9 2002

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Janine Polizzi
Agent for,
EnvirOX, LLC
1938 E. Fairchild Street

Subject: H2Orange2 Concentrate 117

EPA Registration Number 69268-2 Your Notification Dated May 20th, 2002 EPA Received Date May 21st, 2002

Dear Ms. Polizzi:

This notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add the alternate brand name, H2Orange2 Concentrated Household Cleaner, is acceptable.

Your notification has been made a part of the permanent records for this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell Product Manager 33

Regulatory Management Branch I

Antimicrobial Division(7510C)

Please read instructions on reverse before completing form		F0	rm Approved, OM	B No. 2070-006	60, Approval expires 5-31-98
	States	<del>-</del>	Registra	tion	OPP Identifier Number
SEPA Environmental P	rotection And	ancu	Amenda	ent	ļ
	_	and y	X Other		
	n, DC 20460 cotion for Pac	sticide – Sectio	<u></u>		<u> </u>
Company/Product Number	cation for Fes	2. EPA Product M		3. Propos	sed Classification
69268-2		M. Swindell		J `	,—.,
4. Company/Product (Name) H <sub>2</sub> Orange <sub>2</sub> Concentrate 117		PM # 33		X Nor	ne Restricted
Name and Address of Applicant (Include ZIP Code)		6. Expedited Rev			
EnvirOx, LLC 1938 E. Fairchild Street	[	(b)(i), my product 4 to:	s similar or iden	tical in compo	osition and labeling
Danville, IL 61832	ļ	EPA Reg No.			
Check if this is a new address		Product Name	<del></del>		
	Sectio	m - II	<del></del>	-	
Amendment - Explain below	Gectio	<del></del>	d labels in respo	inse to	- <del></del>
		Agency lette	-	-	
Resubmission in response to Agency letter dated	<del></del>	"Me Too" A	-		
X Notification – Explain below		Other – Exp	lein below		
Explanation: Use additional page(s) if necessary. (For S	notion Lond Speti	ion II \			
This is a Notification per PR Notice 98-10 to add an Alterna		•	trated Househo	d Cleaner.	
This notification is consistent with the provisions of PR Not	•	-			
changes have been made to the labeling or the confidential					
violation of 18 U.S.C. Sec. 1001 to willfully make any false		•			pt .
consistent with the terms of PR Notice 98-10 and 40 CFR					
subject to enforcement action and penalties under sections				· · · · · · · · · · · · · · · · · · ·	
	Section			<del></del>	
Material This Product Will be Packaged in:		· · · · · · · · · · · · · · · · · · ·			
Child-Resistant Packaging Unit Packaging Yes Yes	Wate	er Soluble Packagin Yes	9	2. Type	of Container
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	. Size(s) Retail C	Container	<del></del> -	cation of lab	el directions
X Label Container 3	32 ounces		X	On Label On Label ac	companying product
6. Manner in Which Label is Affixed to Product	Lithograph		Other		
· }	Paper glued Stenciled				
	Sectio	n IV	·	<del></del>	·
1. Contact Person (Complete items directly below for ident					
Name Janine M. Polizzi	Title	emational, LLC	Telep	hone No. (in	clude-Area Code)
	Authorized Ac		/03-4	92-2717	
	ication			-6.	Date Application Received
I certify that the statements I have made on this form and all I acknowledge that any knowingly false or misleading statem				•••	A B B
both under applicable law					• • • • • • • • • • • • • • • • • • •
2. Signature	3. Title ChemBen inte	emational, LLC		**: 1:	• (Stamped)
Janunem Docog	Authorized Ag			••••	••••
4-Typed Name	5. Oate				·•
Janine M. Polizzi	May 20, 2002	•			••••
				{	• ••

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.

White - EPA File Copy (Original) Yellow - Applicant Copy



## 1990 OLD BRIDGE ROAD, SUITE 201 LAKE RIDGE, VIRGINIA 22192-2383

DIRECT: 703-492-2717

Main: 703-492-0445

Fax: 703-492-0668

E-Mail:

polizzi@chemreg.com

WEB SITES: www.chemreg.com

www.pesticide.net

JANINE M. POLIZZI

May 20, 2002

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

Attn: Mr. Marshall Swindell (PM 33)

Re:

H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 (EPA Reg. No. 69268-2)

Notification per PR 98-10 to add alternate brand name, H2Orange2 Concentrated

Household Cleaner

Dear Mr. Swindell:

As permitted under PR Notice 98-10, EnvirOx, LLC is adding an alternate brand name, H2Orange2 Concentrated Household Cleaner, to EPA Reg. No. 69268-2. Enclosed please find EPA Form 8570-1 and one (1) copy of the label with the change identified. Please let me know whether you have any questions about this notification, which is submitted on behalf of our client, EnvirOx, LLC.

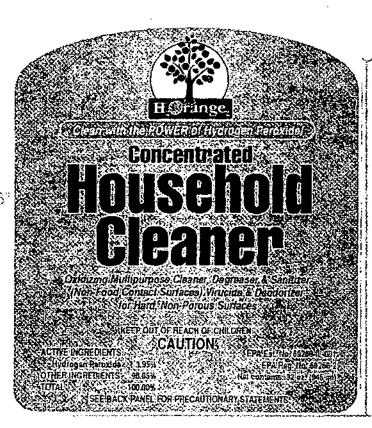
Regards,

Janine M. Polizzi

cc: EnvirOx, LLC

## CONSULTANTS TO SUCCESS\*\*

Over One Hundred and Fifty Years of Combined Experience Assisting Chemical, Pesticide, Bio-Chemical and Life Science Companies on a Wide Range of Issues, Including Regulatory Strategies, Registration, Data Support and Compensation, Quality Assurance, Study Design and Scientific Matters.



#### CONCENTRATE

DIRECTIONS FOR USE it is violation of Federal law to use this product in a manner inconsistent with its labeling.

Enviror: Hydrangey Concentrated Household Cleaner, when used as directed as a sanitizer, kits 98,93% of the following: Staphylococcus eureus, Sathornata cholaressus, Kleistiella pheumonize, Pseutomories agritimosa, Streptococcus learnaise, and Escharichia col. When used as directed as a virudice, Hydrangey Concentrated Household Cleaner kills the following viruses in 5 minutes at morn tamperature (2014-11 G): Hoppes simplex virus Type 2, Influenza Az/Japan. To insure that all bacteries and virel agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

CLEARING: Using the appropriate clashing solution for the type of surface to be treated, thoroughly clean the surface, ellow to eit dry. If needed use additional solution. Replace solution dails.

TO USE AS A SANITIZER AND VIRUCIDE IN BATHROOMS: Add 10 oz. of product concentrate per gallon of variar for siries, leurest, counters, tefnels, toffers (non-west covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where time and soils build up. Replace solution daily. Follow instructions for imprimate, hard, non-porotic surfaces.

OECOCRIZING: For general decodorizing, use 2 parts H<sub>2</sub>Crange<sub>2</sub> Concentrated Household Cleaner to 126 parts water (2 oz / gellon). Apply to here, non-porous surfaces to etiminate generally othersive octors due to epillage from post-octorstomy, post-doctory dressing and larg changes, and other spills such as wise or facal matter, smoke or soot deposits, industrial plant processes, middew and mold surfaces in musty closers. For effective, high level, decodorizing, use 10 parts H<sub>2</sub>Crange<sub>2</sub> Concentrated Household Cleaner to 119 parts water (10 oz / gellon).

TO USE AS A SANITIZER AND VIRUCIDE ON INANIMATE, HARD, NON-POROUS SURFACES: Add 10 ources of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray boalle, pump up pressure sprayer with a coarse spray, don't, sponge or more. Allow surface to remain was for 5 minutes, then, either allow to air day or wide day to remove encess liquid. Heavily solited surfaces should be pre-cleaned with the same solution. Replace solution daily.

3-1/4

3-3/15"

## **CLEANING DILUTIONS**

#### **CLEANING APPLICATIONS**

#### Bathroom surfaces

USE HEAVY-DUTY DILUTION. (10 oz./gal.) Spray sink, faucets, counter, todet, (und floor around todet), tub and shower liberally. Let sit for five minutes then wipe or scrub clean. No rinse is required. Use as daily shower apray to prevent soil buildup. Spray surfaces after shower and let dry.

### Kitchen surfaces

USE HEAVY-DUTY DILUTION. (10 oz.:gal.) Spray and wipe clean. For heavy soils on hood and stoverope, spray and let sit a few manutes then sorub or wipe clean. For odor control in garbage containers, spray lightly before inserting plastic liner.

#### Carper steins

43/16

USE CARPET SPOTTER DILUTION. (2 or./gal.) Before dearing, test a hidden section for color fastness. Remove gross soit, then seek spot and let sit for five to ten minutes. Biot line spot with a clean, soft cloth, Repeat as necessary. For petrolaum-based stains use Super-Duty Dilution (24-48 oz./gal.) and rinse with clean water.

#### Glass surfaces

USE LIGHT-DUTY DILUTION. (1 oz./pal.) Spray surface and wipe clean. It is not necessary to polish the surface dry.

#### Laundry pre-spray

USE SUPER-DUTY DILUTION. (24-48 ozupal.) Yest delizate labrics in tidden area for color fastness. Sock spot and itel on for at least littleon mixutes, then launder or south and rinse as usual.

#### Tough soils.

USE SUPER-DUTY DILUTION. (24-48 oz./get.) Spray the soil, let six a few minutes, then scrub or wipe clean. Use for oil and grease, bugs and tar on outcombiles, driled food residue, and pet soils.

## PRECAUTIONARY STATEMENTS— HAZARDS TO HUMAN AND DOMESTIC ANIMALS

CALITION: Causes moderate eye damaga. Avoid context with eyes, skin or civiling. West inormality with scap and exter after handlag. Avoid consamination of local

After product is divised in accordance with directions for one, salety glasses or other upe protection are not required. Product, other distributes according to directions, in non-limitating, FIRST AID:

IF IN EYES: Hold eye open and mise elosiy and gently with value for 15-20 minutes.
Remove contact losses, if present, sizer the first 5 minutes, tight confully dissing eye.
Call a poison control center or doctorator types

F ON SKIN AND CLOTHING: Take of greanflast distring. Risse sign immediately with pierly of visiter for 15-20 naturals. Call a poison central center of doctor for treatment extract.

Editor.

F SYNALLOVIED: Cell a poison control control dogor immeditary for exament solvice. Have person sip a gites of water if able to swallow. Do not induse vorasing unless told to do so by a poison control career or destry. On our give any original of which to an unconstitute person.

(F DRALED) Move victim to bresh air. If graphisatign), cal 911 or an arthulance, than, give entitied respiration, pretentify mutative-mount, if possible, Cell is recised ground senter or doctor for further treatment solution.

occar for intrinsi resurrent santos.

Note to Physiciant Probable nucusal develop reay constanticate the use of gastric levelop.

STORAGE AND DISPOSAL:

IN CASE OF SPILL: Clean up immedically, To clean up दारे. Asia कर कोठा किएक quantity of water.

STORAGE: On not consuminate vicine, load and or feed by sovege. Store below \$5" F. Keep concentrate away from incompatible materials.

PESTICIDE DISPOSAL: Do not contaminate mater, food or feed by disposal.

CONTAINER DISPOSAL: Compilially empty container. Do not reuse empty containers. Rinso and records or disposa of in tresh,

Manufactured by EnvirOx L.L.C. - Damyle, (linois - 800-281-9804

65

CODING FORM FOR					
FILE SYMBOL/REG NO.				TION CODE_	332)
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Kyle Sibinovic, Agent for Envirox c/o Shaldra, Inc. 4327 Reels Mill Road Frederick, MD 21704-7759

Subject:

H2Orange2 Concentrate 117

EPA Reg. No. 69268-2

Your Notification Dated 3/11/2001

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, to change the registrants address, telephone, and fax, and to add the alternate brand name "H2Orange2 Concentrated Household Cleaner", and to change abbreviate the container sizes from gallon to gal, and ounce to oz, is acceptable.

Your notification has been made a part of the permanent records for this file.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,

Marshall Swindell,

Product Manager Team 33,

Regulatory Management Branch I

Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL

SURNAME

DATE

DATE

Fried - Date

OFFICIAL FILE COPY

## SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 FAX: (301) 695-1409 (301) 695-1200 email: shaldra@starpower.net

Document Processing Desk (NOTIF) Office of Pesticide Programs (7504C) **US Environmental Protection Agency** Room 266A, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA 22202-4501 for

Marshall Swindell Product Manager (33) Regulatory Management Branch I Antimicrobial Program Division (7510W) US Environmental Protection Agency Crystal Mail 2, Room 266A 1921 Jefferson Davis Hwy Arlington, VA 22202

Re:

H2Orange2 117 Concentrate Notification of Address Correction EPA Reg. No. 69268-2 OPP ID# 233388

03-11-2002

Dear Mr. Swindell:

As directed, I am sending you the following notification:

Application for Notification of Address Correction - OPP ID # 233388.

(a) Notification of the address correction for EnvirOx, LLC

To: From: EnvirOx LLC

EnvirOx, LLC 1938 E. Fairchild St. New phone #: 217-442-8596 New fax #:

Box 19-Maple Grove Rd.

217-442-2568

Georgetown, IL 61842 Danville, IL 61832

(b) Addition of the alternate brand name: H2Orange2 Concentrated Household Cleaner.

- (c) Change container sizes to read: gal in place of gallon, oz in place of ounce.
- 2. Copy of the master label with the address correction noted.
- All correspondence is to be sent as usual to the above address to the attention of our agent, Dr. 3. Kyle H. Sibinovic, at her address as given above.

The above correction is the only change made to the label. Except for item 1(c), no other changes have been made since the changes to the First Aid section submitted in October, 2001, and the notification statement as per PR Notice 98-10 is included on the Form 8570-1.

Sincerely yours,

Kyle H. Sibinovic, Ph.D.

Kylidd Solum P321

Agent for Envirox, LLC

Please reed instructions on reverse before completing form	Form Approved. OMB No. 2070-0060. Approval expires 2-28-95
SEPA Environmental Protection A	Registration OPP Identifier Number Qency Amendment 233388
The second section is a second	ir Pesticide: Section [ ]
1. Company/Product Number	2. EPA Product Manager 3. Proposed Classification
4. Company/Product (Nama) 12 Ora in 12 117	PM# 33
5. Name and Address of Applicant (Include ZIP Code)	6. Expedited Review. In accordance with FIFRA Section 3(c)(3)
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Donorell IL 61831	EPA Reg. No.
Check if this is a new address	Product Name
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## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to everage 0.85 hour po response. Including time for reviewing instructions, searching existing dere sources, gathering and maintaining the data needed, and completing and aviewing the collection of information. Send comments regarding the builden estimate or any other espect of this collection of information, including suggestions for reducing this burden, to Chief, information Folicy Branch, (2138), U.S. Environmental Protection Agency, 401 M.Street, SW. 🛬 Washington, DC 20460; and to the Office of Information and Regulatory Affelia. Office of Management and Budget, Washington, DC 220503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration ament, result mission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570.29). Ill not exempted by 40 CFR 152.81 (b) (4)1
- 2 Confidential Statement of Formula (EPA Form 8570-4).
- Formulator's Exemption Statement (EPA Form 8570:27);
- Five copies of draft labeling:
- Three copies of any data submitted;
- 6. Authorization letter where applicable;
- Matrices where applicable...

Submission of Labeling - Labeling should first be submitted in the form of digit labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission of a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5% [1] Inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mount on 8.5 1.1 Inch paper for submission.

Submission of Data. Data submitted in support of this application must be submitted in eccordance with RR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please road the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration ections. Sections 1. III end IV must be completed by the applicant. For applications submitted in connection with amondodirecal stration actions, resubmissions? nouffications, reregistrations, etc. Sections ( II. and IV must be completed by the applicant. Block A. Check the appropriate action for which you are submitting this form.

SECTION I . This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number it one has been assigned by EPA. This number may have been assigned to you as a basio registrant, a digitibutor, or as an establishment. If your product is registered, insert the Product Number.
- EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager
- Proposed Classification Specify the proposed classification of this product?
- Product Name. Enter the complete product name of this pesticide easit will appear on the lebel. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations:
- Name and Address of Applicant . The name of the firm of person and address shown in your application is the person of firm to whom the registration vill be issued. If you are acting in benefit of another parry, you must submit authorization from that parry to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application (
- Expedited Review . FIERA section 3 (c) 3 (B) provides for expedited review of spolications for registration, or amendments to existing registrations that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your explication to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II This section must be completed for all applications submitted to emend the registration only of a currently registered product (Amendment). for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for relegistration and for any other action that partiting to a specific EPA legistered product. This section is not to be used for a new application for the registration.

Subject of submission. Check the applicable block and provide the Agency letter date if appropriate: Provide a brief explanation of the purposets! for the submission, such as "the addition of a site, past or crop (specify)", amend the Confidential Statement of Formula by ..."; "rangistration gubrilssion"; "general label revision of usa directions. Allech a superate page if additional apoce is needed.

SECTION III (Packeting and Container Information). This Section must be completed for all applications submitted in connection with new registration of applicable amendments.

- Type of Packeging Check the appropriate black if your product will be packeged in the indicated packeging types Indicate the size of the individual packets and number per ratell container.
- Type of Retail Container Indigate type of container in which product will be marketed:
- Location of Net Contents Indicate its location of the net contents information for your product
- Sixe(s) of Retail Container Specify the net contents of all retail containers for your product.
- Location of Use Directions Indicate the location of the use directions for your product.
- 6. Manner in which tabel is affixed to product Indicated the method product label is attached to retail container.

烈星和丹女用的 SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration resubmission, me-top, eregistration, etc.:

- 1-5. Self-explanatory.
- EPA Use Only.

(logo)

H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117
OXIDIZING MULTI PURPOSE CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS **SURFACES** 

> **ACTIVE INGREDIENT** Hydrogen peroxide

3.95%

OTHER INGREDIENTS

96.05%

TOTAL

100.00 %

KEEP OUT OF REACH OF CHILDREN

## CAUTION

PRECAUTIONARY STATEMENTS

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 69268-2 EPA Est. No. 69268-IL-001

> ENVIROX, LLC. 1938 E. FAIRCHILD ST DANVILLE, IL 61832

NET CONTENTS: 5 gal (640 oz);1 gal (128 oz, 3784 ml); 32 oz(946 ml)

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced difectly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact muchus membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterifization or high level disinfection.

## **PRECAUTIONARY STATEMENTS**

## HAZARDS TO HUMAN AND DOMESTIC ANIMALS

Caution. Causes moderate eye damage. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Avoid contamination of food.

After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.

### **FIRST AID**

IF IN EYES: Hold eye open. Rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then, continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move victim to fresh air. If not breathing, call 911 or an ambulance, then, give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control venter or doctor for further treatment advice.

## STORAGE AND DISPOSAL

IN CASE OF SPILL: Clean up immediately. To clean up spill, flush area with large quantity of water.

**STORAGE**: Do not contaminate water, food, and or feed by storage. Store below 95°. Keep concentrate away from incompatible materials.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by disposal.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Rinse and recycle or dispose of in trash.

## DIRECTIONS FOR USE

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

H<sub>2</sub>Orange<sub>2</sub> Concentrate 117, when used as directed as a sanitizer, kills 99.99% of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruinosa, Streptococcus faecalis, and Escherichia coli. When used as directed as a virucide, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 kills the following viruses in 5 minutes at room temperature (20+/-1°C): Herpes simplex virus Type 2, influenza A<sub>2</sub>/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

<u>Cleaning:</u> Using appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution, Replace solution daily.

To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces: Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer using a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

To use as a sanitizer and virucide in bathrooms: Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals (non-water covered surfaces), toilets (non-water covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily. Follow instructions for inanimate, hard, non-porous surfaces.

<u>HIV-1:</u> To kill HIV-1 in 5 minutes at room temperature (20-25° C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of **H<sub>2</sub>Orange<sub>2</sub> Concentrate 117** to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

<u>Personal Protection</u>: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned form surfaces and objects before application of diluted product using the Heavy Duty or Super Duty Cleaning Solution.

<u>Contact time</u>: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

Infectious Materials Disposal: Cleaning materials that may contain blood end other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

## Deodorizing

For general deodorizing, use 2 part H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 118 (10 oz / gallon) parts water. Apply to hard, non -porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

## **CLEANING SOLUTION DILUTIONS & APPLICATIONS**

LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)
Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)
General wipe down cleaner
Mopping solution for Bathroom and Kitchen floors
General carpet spot remover

HEAVY DUTY (10 Oz / gal) RED (bottle or label)
Bathroom, shower room, tile & grout cleaner
Urine and garbage odor eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew

SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)
Renovation of tile & grout surfaces
Difficult urine & garbage odor destruction
Scuff marks and stubborn stains
Cleans heavy mold & mildew

### DIRECTIONS FOR CONSUMER LABEL - CLEANING DILUTIONS

## **CLEANING APPLICATIONS**

### Bathroom surfaces

USE HEAVY\_DUTY DILUTION (10 oz/gal). Spray sink, faucets, counter, toilet, (and floor around toilet), tub and shower liberally. Let sit for 5 min, then wipe or scrub clean. No rinse is required. Use as daily shower spray to prevent soil buildup. Spray surfaces after shower and let air dry.

#### Kitchen surfaces

USE HEAVY DUTY DILUTION (10 oz/gal). Spray and wipe clean. For heavy soils on hood and stovetops, spray and let sit a few minutes than scrub or wipe clean. For odor control in garbage containers, spray lightly before inserting plastic liner.

## Carpet stains

USE CARPET SPOTTER DILUTION (2 oz/gal). Before cleaning, test a hidden section for color fastness. Remove gross soil, then soak spot and let sit for 5 to 10 min. Blot spot with a clean, soft cloth. Repeat as necessary. For petroleum-based stains use Super-Duty Dilution(24-48 oz/gal) and rinse with clean water.

#### Glass surfaces

USE LIGHT DUTY DILUTION (1 oz/gal). Spray surface and wipe clean. It is not necessary to polish the surface dry.

## Laundry pre-spray

USE SUPER DUTY DILUTION (24-48 oz/gal). Test delicate fabrics in hidden area for color fastness. Soak spot and let sit for at least 15 min., than launder or scrub and rinse as usual.

## Tough soils

USE SUPER DUTY DILUTION 24-48 oz/gal). Spray soil, let six a few minutes, then scrub or wipe clean. Use for oil and grease, bugs and tar on automobiles, dried food residue and pet soils.

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Shaldra, Inc., Agent for EnvirOx, LLC c/o 4327 Reels Mill Road Frederick, MD 21704-7759

Attention: Kyle H. Sibinovic, PhD

Subject: H

H2 Orange2 Concentrate 117

EPA Registration No. 69268-2

Amendment Application Dated: March 1, 2002

EPA Received Date: February 8, 2002

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records.

Sincerely,

Marshall Swindell

Product Manager (33)

Regulatory Management Branch I Antimicrobials Division (7510C)

Enclosure

CONCURRENCES

SYMBOL SURNAME

DATE

Sem (200.14/100) OFFICIAL FILE COPY

(logo)

H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES

ACTIVE INGREDIENT Hydrogen peroxide

3.95%

OTHER INGREDIENTS

96.05%

TOTAL

100.00 %

KEEP OUT OF REACH OF CHILDREN

## CAUTION

PRECAUTIONARY STATEMENTS

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 69268-2 EPA Est. No. 69268-IL-001

> ENVIROX, LLC. 1938 E. FAIRCHILD ST DANVILLE, IL 61832

ACCEPTED
MAR 1 4 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.6 9268 – Z

NET CONTENTS: 5 gal (640 oz);1 gal (128 oz, 3784 ml); 32 oz(946 ml)

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

## EnvirOx 800-281-9604

## PRECAUTIONARY STATEMENTS

## HAZARDS TO HUMAN AND DOMESTIC ANIMALS

Caution. Causes moderate eye damage. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling. Avoid contamination of food.

After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.

#### FIRST AID

IF IN EYES: Hold eye open. Rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then, continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 to 20 minutes. Call a poison control center or doctor for treatment advice.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF INHALED: Move victim to fresh air. If not breathing, call 911 or an ambulance, then, give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control venter or doctor for further treatment advice.

## STORAGE AND DISPOSAL

IN CASE OF SPILL: Clean up immediately. To clean up spill, flush area with large quantity of water.

STORAGE: Do not contaminate water, food, and or feed by storage. Store below 95°. Keep concentrate away from incompatible materials.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by disposal.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Rinse and recycle or dispose of in trash.

## **DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

H<sub>2</sub>Orange<sub>2</sub> Concentrate 117, when used as directed as a sanitizer, kills 99.99% of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruinosa, Streptococcus faecalis, and Escherichia coli. When used as directed as a virucide, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 kills the following viruses in 5 minutes at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A<sub>2</sub>/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

ACCEPTED

MAR 1 4 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6 9 2 6 8 2



<u>Cleaning:</u> Using appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces: Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer using a coarse spray, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

To use as a sanitizer and virucide in bathrooms: Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals (non-water covered surfaces), toilets (non-water covered surfaces) and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily. Follow instructions for inanimate, hard, non-porous surfaces.

<u>HIV-1</u>: To kill HIV-1 in 5 minutes at room temperature (20-25° C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of **H<sub>2</sub>Orange<sub>2</sub> Concentrate 117** to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

<u>Personal Protection:</u> Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned form surfaces and objects before application of diluted product using the Heavy Duty or Super Duty Cleaning Solution.

Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

<u>Infectious Materials Disposal:</u> Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

## Deodorizing

For general deodorizing, use 2 part H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 to 118 (10 oz / gallon) parts water. Apply to hard, non -porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

MAR 1 4 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 6 9 2 6 8 - 2

#### **CLEANING SOLUTION DILUTIONS & APPLICATIONS**

LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)
Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)
General wipe down cleaner
Mopping solution for Bathroom and Kitchen floors
General carpet spot remover

HEAVY DUTY (10 Oz / gal) RED (bottle or label)
Bathroom, shower room, tile & grout cleaner
Urine and garbage odor eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew

SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)
Renovation of tile & grout surfaces
Difficult urine & garbage odor destruction
Scuff marks and stubborn stains
Cleans heavy mold & mildew

## DIRECTIONS FOR CONSUMER LABEL - CLEANING DILUTIONS

#### **CLEANING APPLICATIONS**

#### Bathroom surfaces

USE HEAVY\_DUTY DILUTION (10 oz/gal). Spray sink, faucets, counter, toilet, (and floor around toilet), tub and shower liberally. Let sit for 5 min. then wipe or scrub clean. No rinse is required. Use as daily shower spray to prevent soil buildup. Spray surfaces after shower and let air dry.

### Kitchen surfaces

USE HEAVY DUTY DILUTION (10 oz/gal). Spray and wipe clean. For heavy soils on hood and stovetops, spray and let sit a few minutes than scrub or wipe clean. For odor control in garbage containers, spray lightly before inserting plastic liner.

## Carpet stains

USE CARPET SPOTTER DILUTION (2 oz/gal). Before cleaning, test a hidden section for color fastness. Remove gross soit, then soak spot and let sit for 5 to 10 min. Blot spot with a clean, soft cloth. Repeat as necessary. For petroleum-based stains use Super-Duty Dilution(24-48 oz/gal) and rinse with clean water.

#### Glass surfaces

USE LIGHT DUTY DILUTION (1 oz/gal). Spray surface and wipe clean. It is not necessary to polish the surface dry.

#### Laundry pre-spray

USE SUPER DUTY DILUTION (24-48 oz/gal). Test delicate fabrics in hidden area for color fastness. Soak spot and let sit for at least 15 min., than launder or scrub and rinse as usual.

## Tough soils

USE SUPER DUTY DILUTION 24-48 oz/gal). Spray soil, let six a few minutes, then scrub or wipe clean. Use for oil and grease, bugs and tar on automobiles, dried food residue and pet soils.

ACCEPTED

MAR 1 4 2002

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 69268—2

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#### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409 email: shaldra@starpower.net

Marshall Swindell Product Manager (33) Regulatory Management Branch I Antimicrobial Program Division (7510W) US Environmental Protection Agency Crystal Mall 2, Room 266A 1921 Jefferson Davis Hwy Arlington, VA 22202

Copies of EnvirOx labels for:H2Orange2 Re: 117 Concentrate (5 copies each) with correct address on label for stamping.

EPA Reg. # 69268-2

03-11-2002

Dear Mr. Swindell:

Following are 5 copies of the above referenced label with the correct address of EnvirOx, LLC on the first page. The states are requesting that we obtain a stamped label from your office with this address correction on it to accompany the state applications.

We greatly appreciate your providing us with the needed stamped labels for that use.

Thank you for your assistance with this matter.

Sincerely yours, Kelett Shenr MD

Kyle H. Sibinovic, Ph.D.

Agent for EnvirOx, LLC

lease read instructions on p	reverse before completing for	n	F	orm Approve	d, OMB No.	2070-0060	D. Approval expires 2-28-95
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	Appli	cation for	Pesticide	Section	1		
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Company/Product (Name)	Concentra	117 **	РМ# 33				None Restricted
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Please Read All Instructions Refore Completing this Form (Form must be typed) Form Approved. SMS No. 2070-0044, Approved Expires 1-31-86

**SFPA** 

## **Environmental Protection Agency**

Office of Perticide Programs (7505C)
Washington, DC 20460

United States

Notice of Supplemental Distribution of a Registered Pesticide Product

### Instructions

After a registrant has obtained final registration for the basic product, the registrant may then supplementally distribute his/her product. One form must be submitted for each distributor product and must be signed by the distributor involved. The basic registration number and the distributor company number must be shown.

If a registrent has a potential distributor who does not have a company number sesigned, she/he should have the distributor apply, on fetterhead stationary, to the Registration Division to have a number assigned prior to submitting this form to the apency.

This Notice of Supplemental Distribution must be submitted by the basic registrant. The completed form must have the concurrence and signature of both the registrant and the distributor.

EPA Registration Number of Product Distributor Company Number 69268-2 6 73835 Note: Do not submit distributor product labels Name of Registered Product (basic product name accepted by EPA) Distributor Product Name H2 Orange2 117 (Manual Dilution) H2 Orange 2 117 (Manual Dilution) Home and Address of Distributor (Type: Include ZIP code) PERFORMANCE FOOD GROUP 12500 WESTCREEK PARKWAY RICHMOND, VA 23220 Read All Conditions Before Signing 1. The distributor product must have the same composition as the basic product. 2. The distributor product must be manufactured and packaged by the same person who manufactures and packages the registered basic product. 3. The labeling for the distributor product must bear the same claims as the basic product, provided, however, that specific claims may be deleted if by doing so, no other changes to the label are necessary. The product must remain in the manufacturer's unbroken container. The label must bear the EPA registration number of the basic product, followed by a hyphen and the distributor's company number. 6. Distributor product labels must bear the name and address of the distributor qualified by such terms as "packed for...", distributed by..."; or "sold by..." to show that the name is not that of the manufacturer. 7. All conditions of the basic registration apply equally to distributor products. It is the responsibility of the basic registrant to see that all distributor labeling is kept in compliance with requirements placed on the basic product. Distributor We intend to market our product under the Distributor Product Nama specified above, subject to the conditions specified on this Notice. Registrant ly distribute and self the Distributor Product specified share, subject to the condition egree that the distributor



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

MAY 0 9 2000

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Shaldra, Inc. 4327 Reels Mill Road Frederick , MD 21704-7759

Attention: Kyle H. Sibinovic

Subject: H<sub>2</sub> Orange 2 Concentrate 117

EPA Registration Number 69268-2 Your Submission Dated April 27th, 2000 EPA Received Date April 28th, 2000

This will acknowledge receipt of your notification to add the alternate brand name "H2 Orange<sub>2</sub> 117 (Manuel Dilution)" submitted under the provisions of FIFRA section 3(c)9. based on a review of the submitted material, the following comments apply.

The application is acceptable and the notification has been made a part of the records for this file.

Sincerely,

Product Manager 33

Regulatory Management Branch I Antimicrobial Division(7505C)

### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409 email: shaldra@starpower.net

Marshall Swindell **Product Manager Team 33** Regulatory Management Branch I Antimicrobial Program Division (7510C) **US Environmental Protection Agency** Crystal Mall 2, Room 266A 1921 Jefferson Davis Hwy Arlington, VA 22202

Re: Notification of Alternte Brand Name for Product H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 EPA Reg. No. 69268-2 OPP ID# 233362 Response to letter of 04-05-2000 04-27-2000

Dear Mr. Swindell:

Enclosed please find the following:

Transmittal letter. 1.

Application for Pesticide Notification - OPP ID # 233362, for the addition of alternate brand name, with 2. notification statement.

To be consistant with the wishes of the State of California, the sponsor, EnvirOx, LLC, wishes to add the atternate brand name for this product of: H<sub>2</sub>Orange, 117 (Manuel Dilution).

This notification is filed in accordance with PR Notice 95-2, Section II. A.1, and is consistant with 98-10. As it is apparent that the initial submission in which the notification statement was attached as a separate page and was apparently lost, the notification statement is located on form 8570-1.

Thank you for your attention to this notification.

Estelin PhD

Sincerely yours,

Kyle H. Sibinovic, Ph.D.

Agent for EnvirOx, LLC

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060: Approvel expires	2-28-95
Chited States Registration OPP Identifier Nur  Page 1 Amendment 23336  Washington, DC 20460  OPP Identifier Nur  Other	nber 3
Application for Pesticide - Section I	The second of the
1. Company/Product Number Coff 2 6 8 4 2 EPA Product Manager 3 Proposed Classification	n 310
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5 Name and Address of Applicant (Include ZIP Code)  6 Expedited Review In accordance with FIFRA Section 3(b)(i); my product is similar or identical in composition and lab	
EPA Reg. No. 1	
Product Name  Section : II	
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3. Location of Net Contents Information 4. Sizele) Retail Container 5. Location of Label Directions On Label On Label	
6. Manner in Which Lebel is Affixed to Product Lithograph Paper gived Stenciled	
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Name	C 00
Certification  I certify that the statements have made on this form and all attechments thereto are true, accurate and complete  I acknowledge that any knowingly false of misleading gratement may be punishable by line or imprisonment of the list	
2. Signature  Labella 170	
4. Typed Name Keyle H. Sigin-ovil PhD  5. Data	
EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete.	cent Copy

### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to everage 0.85 hour r response, including time for reviewing instructions, segrabling existing date courses, the haring and maintaining the data needed, and completing and raviowing the collection of information. Send comments regarding the builden estimate or any other espect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Brench. (2138). U.S. Environmental Protection Agency, 401 M Street, SW Washington, DC 20460; and to the Office of Information and Regulatory Affairs. Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment resubmission, to applications for notifications, final printed labeling, reregistration; etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application: 🖈

- Certification with Respect to Citation of Data (EPA Form 8570 29). [If not exempted by 40 CFR 152.81 (b) (4)]:
- Confidential Statement of Formula (EPA Form 8570;4);-
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of droft labeling;
  5. Three copies of any date submitted;
- 6. Authorization letter where applicable;
- 7. Matrices where applicable.

Submission of Labeling - Labeling should first be aubmitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup tabels significantly smaller than 8.5 x 11 inches should be mounted an 8.5. x 11 inch paper for submission. ., 35000万米。蒋石、

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5

1 1 64 1 1 1 1 1 1 W. SPECIFIC INSTRUCTIONS: Flease read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application, For applications submitted in connection with New Ragistration actions, Sections I, III. and IV must be completed by the applicant. For applications submitted in connection with amended reredistration actions, resubmissions, notifications, reredistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form

SECTION 1 - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basio registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- EPA Product Manager If known, till in the name and PM number of the EPA Product Manager.
- Proposed Classification Specify the proposed classification of this product
- Product Name . Enter the complete product name of this posticide as it will appear on the label. The name must be specific to this product ordy
- Duplication of names is not permitted among products of the same company. Of not include any brand name or company line designations.

  5. Name and Address of Applicant. The name of the firm of person and address shown in your application is the person or firm to whom the registration will be issued. If you are ecting in behalf of enother party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or emendments to existing registrations, that are similar or identical to other pasticide products that are currently registered with the ERA; in order for your application to be alighble for expedited review, you must provide us with the EPA Registration Number and product name of the product you beliave is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses:

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amondment), for a resubmission in response to an Agency letter, for notifications to the Agency; for the submission of final printed labeling, for peregistration and for any other action that pertains to a specific EPA registered product. This section is not to be used for a new application for registration,

Subject of submission - Check the applicable block and provide the Agency letter date it appropriate. Provide a prior explanation of the purposale) for the submission, such as "the addition of a site, post or crop (specify)", "amend the Confidential Statement of Formula by..."; "reregistration submission"; "paneral label revision of use directions." Attach a separate page it additional space is needed.

SECTION III (Pechaging and Container Information) - This Section must be completed for ell applications submitted in connection with nev registration or applicable amendments. 10 - 4 Fr. 6

- Type of Packaging . Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number por retail container.
- Type of Retall Container Indicate type of container in which product will be marketed.
- Location of Net Contents Indicate the location of the net contents information for your product
- Sixelel of Retail Container. Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions : Indicate the location of the use directions for your product.
- 5. Manner in which label is affixed to product Indicated the method product label is affached to retail container

SECTION IV (Caribo (Roint) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission; "me-too," reregistration; etc.

- 1-5. Self-exclanatory
- EPA Use Only.

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SUBMISSION BAN	R CODE # 55 17409	REVIEWER K. Leady - Munk
CODING FORM FO	R APPLICATIONS FOR	REGISTRATION/AMENDMENT

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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

APR 5 2000

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Shaldra, Inc. 4327 Reeds Mill Road Frederick, MD 21704-7759

Attention: Kyle H. Sibinovic, Ph.D.

Subject: H2 Orange 2 Concentrate 117

EPA Registration Number 69268-2 Your Submission Dated March 16, 2000 EPA Received Date March 17, 2000

This is to acknowledge receipt of your notification to add the additional brand name of H<sub>2</sub> Orange <sub>2</sub> 117. This notification is unacceptable due to the omission of the notification statement as per PR Notice 98-10 and EPA regulations 40CFR 152.46.

Resubmit a revised EPA form 8570-1 in which the appropriate notification statement as per PR Notice 98-10 appears in Section II under the subheading "Explanation".

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

Marshall Swindell

Product Manager 33

Regulatory Management Branch I Antimicrobial Division (7505C)

### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409 email: shaldra@starpower.net

Marshall Swindell
Product Manager Team 33
Regulatory Management Branch I
Antimicrobial Program Division (7510C)
US Environmental Protection Agency
Crystal Mall 2, Room 266A
1921 Jefferson Davis Hwy
Arlington, VA 22202

Re: Notification of Alternte Brand Name for Product H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 EPA Reg. No. 69268-2 OPP ID# 233357 03-16-2000

Dear Mr. Swindell:

Enclosed please find the following:

1. Transmittal letter.

2. Application for Pesticide Notification - OPP ID # 233357, for the addition of alternate brand name.

To be consistent with the wishes of the State of California, the sponsor, EnvirOx, LLC, wishes to add the alternate brand name for this product of: H<sub>2</sub>Orange<sub>2</sub> 117 (Manuel Dilution).

This notification is filed in accordance with PR Notice 95-2, Section II. A.1.

Thank you for your attention to this notification.

Sincerely yours,

Kyle H. Sibinovic, Ph.D.

Klewden Pro

Agent for EnvirOx, LLC

•<u>..</u>

PIJsse read instructions on reverse before completing form.	Form Approved. OMB No. 2070-0060, Approval expires 2-28-95
SEPA Environmental Protection Age Weshington, DC 20480	<b>∠</b> Other <b>∠</b> 200 30 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2
1. Company/Product Number 69268-2	
4 Company/Product (Name) HyOtange & Concanhate 117	2. EPA Product Manager 3. Proposed Classification M. Mar shell Swindel V. None Restricted
5. Name and Address of Applicant (Include ZIP Gode)  Envir Ox, LLC  Maple Grove Rd	6 Expedited Review: In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:
George Foron IL 61846	EPA Reg No.
	tion ille
Amendment - Explain balow.  Resubmission in response to Agancy latter dated  Notification - Explain below.	Property of the second
The state of the s	nanuel Dilutos
	ion - III
3 Location of Net Contents Information 4. Size(s) Retail Contain	ner S Location of Label Directions On Label On Labeling accompanying product
6. Manner in Which Label is Alfrixed to Product - Lithograph Paper glued Stendled	Other Man Water and American Control of the Control
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1: Contact Point (Complete items directly below for identification of Indivi-	Telephone No. (Include Area Code)
Certification  I certify that the statements I have made on this form and all attach leaknowledge that any knowingly false or misleading statement ma both under applicable law.	- 東京・・グラッと、サードをからも、アード・Activityに呼吸れる。2. からばんが生物。2. 世界を担心を重要を重要を重要を発する。 根据学者であってい
2. Signature Sabli Rivin, PhD 3. Title	Agant
4. Typed Name 5. Date Kyle H. SibiNovic, PhD. 0	3-16-00

### PARERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to overage of 85 hour by response, including time for reviewing instructions, searching existing data sources, gethering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate of any other aspect of this collection of information, including suggestions for reducing this burdon, to Chief, informetion Policy Branch, (2138), U.S. Environmental Protection Agency, 401 M. Street, SW, Washington, DC 20460; and to the Office of Internation and Regulatory Allers. Office of Management and Budget Westington, DC 20503

INSTRUCTIONS: This form is to be used for all applications for new registration, and use raregistration, amendment, resubmission, to application for notifications, final printed labeling, relegistration, etc....In order to process an application for a new registration submitted on this form: the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR(152-81 (b) (4)]: 1-4-3-4-4-4
- Confidential Statement of Formula (EPA Form 8570-4);
- Formulator's Exemption Statement (EPA Form 8570-27)
- Five copies of draft tabeling; 4
- Three copies of any data submitted;
- 8. Authorization letter/where applicable;
- 7. Matrices where opplicable.

Submission of Labeling Labeling should first be submitted in the form of draft labels with all applications for new-registrations. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If propered for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission,

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 88-5.

SPECIFIC INSTRUCTIONS: Please reed the instructions listed gelow before completing this application: First determine the type of registration action, listed in Block A, for which you are submitting this epplication. For applications submitted in connection with New Registration actions, Sections [] [] and IV must be completed by the applicant. For applications submitted in connection with amended relegible in a completed by the applicant. For applicable submitted in connection with a first property of the complete of the complete of the connection of the natifications, reregistrations, etc., Sections I. III and IV must be completed by the applicant Block A. Check the appropriate action for which you are submitting this form.

SECTION 1 This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, it one has been assigned by EPA. This number may have been assigned to you as besic registrant, a distributor, or se an establishment. If your product is registered; insert the Product Number,
- EPA Product Manager. If known, till in the name and PM number of the EPA Product Manager.
- Proposed Classification Specify the proposed classification of this product.
- Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

  Name and Address of Applicant. The name of the firm or person and address shown in your application is the person of firm to whom the 4-3.
- rogistration will be issued. If you are acting in behalf of enotine party you must submit authorization from that party to act tor them intregistration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in, all registration matters. The name and complete mailing address of such an egent must accompany this application.
- Expedited Review FIFRA section 3 (c) 3 (B) provides of supplications for registration, or emendments to existing registration that are similar or identical to other pasticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical. your product. The product must be similar or dantical in both formulation and labeled uses

SECTION II This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resultmission in response to an Agency letter, for notifications to the Agency for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

Subject of submission - Check the applicable block and provide the Agency letter date it appropriate. Provide a brief explanation of the purpose(s) for the submission such as "the addition of a site, past of crop (spacify)"; amend the Confidential Statement of Formula by the addition of a site, past of crop (spacify). submission" : 📲 📲 📲 file and label revision of use directions. Attach a ceparate page if additional apoce is needed:

SECTION III (Rackeding and Container information) - This Saction must be completed for all applications submitted in confection with new **"我们的时候**"。苏轼 registration or applicable amendmonts 🐇 % ENT DIVERSO

- Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types indicate the pie of the individual packets and number per retell container.
- Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Location of hat Christine Indicate the location of the net contents information for your product as
- Sight of Retail Container Specify the net contents of all retail containers for your product.
- Tocation of Uso Directions Indicate the location of the use directions for your product; -
- 6. Manner in which label is affixed to product Indicated the method product label is attached to retail container

Tay self as SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me too," reregistration, etc.

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- EPA Use Only.

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RESPONSE CODE 17

RESPONSE DATE 1/31/2000 V

Alphen LLC P. O. Box 19 Maple Grove Road Georgetown, IL 61846

Mailed To:

Kyle Sibinovic, Agent For Alphen, Inc.

Shaldra, Inc.

4327 Reels Mill Road Frederick, MD 21704-7759

RE:

EPA Reg. No. 69268-2

H ,Orange , Concentrate 117 Your Amendment Dated 8/3/99

The Amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to submit four new acute toxicology studies in support of a change of the Signal Word from "DANGER" to "CAUTION", is acceptable, providing that you make the following label changes listed in this letter.

A copy of the label stamped "Accepted With Comments" is enclosed for your records.

### SIGNAL WORD CHANGE APPROVAL BASIS

This product, and the companion product (EPA Reg. No. 69268-1), were originally registered based on the "Cite All" method of support. Thus, product specific acute toxicology studies were never submitted or reviewed for either product. The "Signal Word", "Precautionary Statements", and "Statement of Practical Treatment" for both products were originally assigned based on the "Peroxy Compounds" RED, and similar "Me Too" registered products.

The four acute toxicology studies you submitted with your Amendment are acceptable (see attached reviews) and apply to both EPA Reg. No. 69268-1 (8% hydrogen peroxide), and EPA Reg. No. 69268-2 (4% hydrogen peroxide). The test substance used was the formula for EPA Reg. No. 69268-1 (8% hydrogen peroxide). The acute toxicology categories for this product, and for the EPA Reg. No. 69268-1 are as follows:

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### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

### LABEL CHANGES

You must submit five copies of a revised final label which incorporates the following changes. Because the newly established acute toxicology categories above apply to both EPA Reg. No.'s 69268-1 and 69268-2, you should also submit an Amendment for EPA Reg. No. 69268-1 requesting a change of the "Signal Word" and other label changes listed below. Please include a copy of this letter with your submission.

### Required Label Changes

1. Based on the acute toxicology categories and the EPA "Label Review Manual", you must change the "Precautionary Statements" to read exactly as follows.

"Caution. Causes moderate eye irritation. Harmful if swallowed, absorbed through the skin, or inhaled. Avoid contact with eyes, skin, or clothing. Wash thoroughly with soap and water after handling."

- 2. Delete the sentence, "Product, after dilution according to directions, is non-irritating."
- 3. Based on the acute toxicology categories and the EPA "Label Review Manual", you must change the "Statement of Practical treatment" to read in the following order, exactly as follows using boldface and caps.

"IF IN EYES: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention."

"IF ON SKIN: Wash with plenty of soap and water. Get medical attention."

"IF SWALLOWED: Call a doctor or get medical attention. Do not induce vomiting or give anything by mouth to an unconscious person. Drink promptly a large quantity of milk, eggwhites, gelatin solution, or if these are not available, drink large quantities of water. Avoid alcohol."

"IF INHALED: Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth-to-mouth. Get medical attention."

Note To Physician: Probable mucosal damage may contraindicate the use of gastric lavage."

- 4. Delete the sentence, "In case of contact with product concentrate."
- 5. On page 3 of the label, the word "officier" is mispelled.

SYMBOL SURNAME DATE

DATE

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,

Marshall Swindell,

Product Manager Team 33,

Regulatory Management Branch I

Antimicrobials Division (7510C)

SYMBOL.
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DATE

EPA Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

(logo)

H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES

ACTIVE INGREDIENT Hydrogen peroxide

3.95%

OTHER INGREDIENTS

96.05%

TOTAL

100.00 %

ACCEPTED with COMMENTS in EPA Letter Dated:

KEEP OUT OF REACH OF CHILDREN

JAN 3 1 2000

### CAUTION

PRECAUTIONARY STATEMENTS

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pessicide, registered under EPA Reg. No.

69268-2

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 069268-2 EPA Est. No. 069268-IL-001

> ALPHEN, INC. MAPLE GROVE ROAD GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact nucleus membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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### PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMAN AND DOMESTIC ANIMALS

Caution.-Undiluted product concentrate causes moderate eye damage. Avoid contact with eyes, on skin or clothing. Avoid contamination of food. Wash thoroughly with soap and water after handling.

Product, after dilution according to directions, is non-irritating.

### STATEMENT OF PRACTICAL TREATMENT

In case of CONTACT with product concentrate

If in eyes: Flush immediately with plenty of cold water. Remove contact lenses. Get medical attention if irritation persists.

If on skin: Immediately wash with plenty of soap and water. Get medical attention if irritation occurs and persists.

If swallowed: Promptly drink large quantity of water. Avoid alcohol. Do not induce vomiting. Never give anything by mouth to an unconsious person.

### STORAGE AND DISPOSAL

IN CASE OF SPILL: Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE**: Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL**: Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

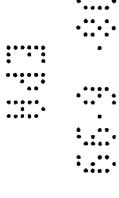
**CONTAINER DISPOSAL**: Completely empty container. Do not reuse empty containers. Leave empty plastic bag in original box and discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.

ACCEPTED with COMMENTS in EPA Letter Dated:

JAN 3 1 2000

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

69268-2





### DIRECTIONS FOR USE

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

Alphen 117, when used as directed as a sanitizer, kills 99.99% or more of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruinosa, Streptococcus faecalis, and Escherichia coli. When used as directed as a virucide, Alphen 117 kills the following viruses in 5 minutes or less at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A<sub>2</sub>/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

1-Step Cleaning and Sanitizing: Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

To use as a sanitizer and virucide in bathrooms: Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals, tollets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily.

To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces: Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

HIV: To kill HIV in 5 minutes at room temperature (20-25° C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of Alphen 117 to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned form surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officier.

Deodorizing

For general deodorizing, use 2 part Alphen 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts Alphen 117 to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

ACCEPTED with COMMENTS in EPA Letter Dated:

JAN 3 1 2000 Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

69268-2

100

### **CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute with Alphen's Dispensing System Only)

LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)
Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)
General wipe down cleaner
Mopping solution for Bathroom and Kitchen floors
General carpet spot remover

HEAVY DUTY (10 Oz / gal) RED (bottle or label)
Bathroom, shower room, tile & grout cleaner
Urine and garbage oder eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew

SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)
Renovation of tile & grout surfaces
Difficult urine & garbage odor destruction
Scuff marks and stubborn stains
Cleans heavy mold & mildew

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JAN 3 1 2000

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

69268-2

101

### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

ALPHEN, INC. P.O. BOX 19 GEORGETOWN, IL 61846

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 08/06/99. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

#### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Marshall Swindell Product Manager PM33 Antimicrobial Program Division (7510W) US Environmental Protection Agency Crystal Mall 2, Room 266A 1921 Jefferson Davis Hwy Arlington, VA 22202

448926-00

Re: Resubmission and Submission Toxicology results with label change for product H<sub>2</sub>Orange, Concentrate 117 EPA Reg. No. 69268-2 OPP ID# 233358 08-03-1999

Dear Mr. Swindell:

### Enclosed please find the following:

Transmittal letter.

Application for Pesticide Notification - OPP ID # 233358. 2.

Certification with Respect to Citation of Data.

Formulator's Exemption Form. 3.

Copy of the matrix for this product.

Three copies each of the following volumes: Volume 1: Acute Eye Irritation in Rabbits (resubmission)

Volume II: Acute Dermal Irritation in Rabbits (resubmission)

44892603

Volume III: Acute Oral Tiloxicity/LD50 in Rats (new)

Acute Dermai Toxicity in Rabbits/LD 50 in rabbits. (new) 44892604 Volume IV:

6. Five (5) copies of amended label.

Volumes I and II were originally submitted on 04-30-1999, but are apparently missing as they did not reach your section. Volumes III and IV are copies of studies currently under review in California as part of Alphen's submission to that state. As recommended by Mr. Kish, we are submitting all four studies at this time.

The results of the eye irritation studies (Volume 1) clearly permit the modification of the label Signal Word to CAUTION as the product falls in Category III. The sponsor wishes to amend the label for this product as given in the attached five label copies. The dermal irritation study using the more concentrated product, H2Orange 2 Super Concentrate 112, showed the product was not a dermal irritant. Therefore, this product would fall into Catagory IV for Dermal Irritation, but the sponsor proposes to maintain the Catagory III wording.

We would appreciate your prompt review of these studies. The sponsor will have to print new labels for this product and would like to use the new wording for the precautionary statements and Signal word at that time.

If you have questions regarding this submission, please contact Kyle H. Sibinovic, Ph.D. at the above telephone number. Thank you for your attention to this submission.

Cleb Lbi PAO

Kyle H. Sibinovic, Ph.D.

Agent for Alphen, LLC

Please read instructions on reverse before completing form.	Form Approved, OMB No. 2070-0	060. Approvel expires 2-28-95
SEPA Environmental Protection Age Washington, DC 20460	Registration	OPP Identifier Number
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H20 range 2 Concentrate 1977	M 33 3 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	
5. Name and Address of Applicant (Include ZIP Code)  Alphen, LLC  Po Box 19 - maple Grove Rd  Goorgatown IL be By b  Check If this is a new address	6. Expedited Review. In accordance w (b)(i), my product is similar or identical in to: EPA Reg. No. Product Name	
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Kyle H SiBinovic, PhD	) <b>8-</b> 03-99.	104

### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to everage 0.85 hour per response. Including time for reviewing instructions, searching existing data sources, gethering and mainteining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other espect of this collection of information, including suggestions for reducing this burden, to Chief. Information Policy Brench (2138), U.S. Environmental Protection Agency 401 M Street, SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resulting solonities for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, this following material must accompany the application:

- Cortification with Respect to Citation of Data (ERA Form 8570-29). (If not exempted by 40 CFR 152.81 (b) (4));
- 2. Confidential Statement of Formula IEPA Form 8570-41:
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- 4. Five copies of draft labeling:
- 5. Three copies of any data submitted;
- Authorization letter where applicable;
- 7. Matrices where applicable."

Submission of Labeling - Labeling should first be submitted in the form of distribute with all applications for new registration. Such distributes may be in the form of typed label text on 8.5 x 11 inch page; for submission of a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inches should be mounted on 8.5 x 11 inches should be mounted on 8.5.

Submission of Data - Date submitted in support of this application must be submitted in accordance with PR Notice 86-5

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this epplications applications applications with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

Block A - Check the appropriate action for which you are submitting this form:

SECTION I - This section must be completed, as applicable, for all registration actions.

- 1. Compeny/Product Number Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
- 2. EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4. Product Name Enter the complete product hama of this pesticide as it will appear on the label. The name must be specific to this product only
- Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.

  5. Name and Address of Applicant. The name of the firm or person and address shown in your application is the person or firm to whom the person or firm to whom the registration will be issued. If you are scring in behalf of another party you must submit authorized from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 8. Expedited Review- FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or emendments to existing registrations, that are similar or identical to other posticide products that are currently registered with the EPA. In order for your application to be aligned appendited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II This section must be completed for all applications submitted to smend the registration only of a currently registered product.

(Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA registered product. This section is not to be used for a new application for registration.

1× Subject of submission. Check the applicable block and provide the Agency letter date it appropriate. Provide a brief explanation of the purposate)

(for the submission, such as "the addition of a site, post or crop (specify)": "smend the Confidential Statement of Formula by..." Freedistration

submission": "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information). This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging. Check the appropriate block if your product will be packaged in the indicated packaging types.
  Indicate the size of the individual package and number per retail container.
- 2. Type of Ratell Container Indicate type of container in which product will be marketed.
- 3. Location of Net Contento Indicate the location of the net contents information for your product.
- 4. Size(s) of Retail Container Specify the net contents of all retail containers for your product.
- 5. Location of Use Directions indicate the location of the use directions for your product.
- 6. Manner in which the stilled to product -indicated the method product label is attached to retail container

SECTION IV (Contact Point). The Section must be completed for all applications for Registration actions, i.e., new products registration, resultmission, me too, reregistration, etc.

- 1-5. Self-explanatory
- 6. EPA Use Only.

105

### SHALDRA; INC 4327 REELS MIEL-RD \_ FREDERICK MD 21764-1759 (301) 695-1200 \_ FAX: (301) 695-1409 = \_\_\_\_

Marshall Swindeli
-Product Manager PM33
-Antimicrobial Program Division (7510W)
US Environmental Protection Agency
Crystal Mall 2, Room 266A
1921 Jefferson Davis Hwy
Adlington, VA 22202

Re: Submission Toxicology results with request for label change for product H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 EPA Reg. No. 69268-2 OPP-ID# 233355 04-30-1999

Dear Mr. Swindell:

Enclosed please find the following:

- 1. Transmittal letter.
- Application for Pesticide Notification OPP ID # 233355.
- Certification with Respect to Citation of Data.
- 3. Formulator's Exemption Form.
- 4. Copy of the matrix for this product.
- 5. Three copies each of the following volumes:.

Volume I:

Acute Eye Irritation in Rabbits.

Volume II:

Acute Dermal Irritation in Rabbits

Five (5) copies of amended label.

The results of the eye irritation studies (Volume I) clearly permit the modification of the label Signal Word to CAUTION as the product falls in Category III. The sponsor wishes to amend the label for this product as given in the attached five label copies. The dermal irritation study using the more concentrated product, H2Orange 2 Super Concentrate 112, showed the product was not a dermal irritant. Therefore, this product would fall into Catagory IV for Dermal Irritation, but the sponsor proposes to maintain the Catagory III wording.

If you have questions regarding this submission, please contact Kyle H. Sibinovic, Ph.D. at the above telephone number.

Thank you for your attention to this submission.

Sincerely vours

Kyle H. Sibinovic, Ph.D. Agent for Alphen, LtC

Form Approved OMB No. 2070-0060.



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY = 401 M Street, S.W. WASHINGTON, D.C. 20460

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comments regarding burden estimate or any other aspect of this collection of information, including sugger Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., W. On not send the completed form to this address.	estions for reducing the burden to: Director, OPPE- ashington, DC 20460.
Certification with Respect to Citation of	Data
Applicant's/Registrant's Name, Address, and Telephone Number Georgetown 1b.  Alphen, LLC P.O. Box19-Maple Grove Rd. 301-695-1200	EPA Registration Number/File Symbol 69268-72
Active Ingredient(s) and/or representative lest compound(s)  Hydrogen_Peroxide	Date 04-30-99
General Use Pattem(s) (list all those claimed for this product using 40 CFR Rari 158)  Step Tegreaser, sanitizer, virucide and deodorizer for hard surfaces	Product Name HzOrangez Concentrate 117
NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled to it this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).	r all the same uses on your label, you do not need to
I am responding to a Data-Call-In Notice, and have included with this form a list of companies se be used for this purpose).	nt offers of compensation (the Data Matrix form should
SECTION I: METHOD OF DATA SUPPORT (Check one m	ethad only)
a first of companies sent offers of compensation (the Data Matrix form- under the	g the selective method of support (or cite-all option- selective method), and have included with this form-a d list of data requirements (the Data Matrix form must be
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i certify that this application for registration, this form for reregistration, or this Data-Call-In response. In addition, if the cities indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the prosupported by all data in the Agency's files that (1) concern the prosupported by all data in the Agency's files that (1) concern the prosupport of this product, or one or more of the ingredients in this product, and (2) is a type of data that requirements in effect on the date of approval of this application if the application sought the initial registratures.  I certify that for each exclusive use study cited in support of this registration or reregistration, that the written permission of the original data submitter to cite that study.  I certify that for each study cited in support of this registration or renegistration that is not an exclusive with the original data submitter to use the study in support of the compensation have expired for the study, (d) the study is in the public literature; or (e) I have notified in writered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; are amount and terms of compensation, if any, to be paid for the use of the study.  I certify that in all instances where an offer of compensation is required, copies of all offers to pay accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. I understand that the Agency may initiate action to deny, cancel or series.  I certify that the statements I have made on this form and all attachments to it are true, knowlingly false or misleading statement may be punishable by fine or imprisonment or both understand that the punishable by fine or imprisonment or both understand that the punishable by fine or imprisonment or both understand that the punishable by fine or imprisonment or both understand that the punishable by fine or imprisonment or both understand that the punishabl	all option or cite-all option under the selective method is perties or effects of this product or an identical or would be required to be submitted under the data tion of a product of identical or similar composition and at I am the original data submitter or that I have obtained its application; (c) all periods of eligibility for ting the company that submitted the study and have at (ii) to commence negotiations to determine the symmetry upon request. Should I fall to produce such juspend the registration of my product in conformity with accurate, and complete. I acknowledge that any
Signature Kylikhelmen hR Date 04-30-99	Typed or Printed Name and Triba Kyle H. Sibinovic, PhD. Agent

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

Yellow - Applicant copy

White - EPA copy

EPA Form 8570-27-(Rev. 7-91)

# United States Environmental Protection Agency Washington, DC 204600 Formulator's Exemption Statement

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Applicant's Name and Address.	(1) 15. 一次多级最级的	A File Symbol/Registration Number (16.)
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- 10		other =
As an authorized representative of the app	olicant for registration of the p	product identified above, I here certify that:
(1) This product contains the following	active ingredient(s):	•
(3) Indicate by checking (A) or (B) belo (A) An accurate Confidential Statem attached to this statement. That for product name, the source of the act	FRA Section 3, is purchased uct is proposed to be labeled with which paragraph applies: sent of Formula (EPA Form 85 rmula statement indicate, by clive ingredient(s) listed in para OR ormula (CSF) (EPA Form 8576 and contans the information research contans the information research contans the information research.	by us from another producer, and is labeled (70-4) for the above identified product is company name, registration number, and 19 (1).  9-4) referenced above and on file with the EPA equired on the current CSF.
		Source
Active Ingredient	Product Name	Registration Number
*Product ingredient source inform	nation may be entitled to	confidential treatment* ••••••
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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

perwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate of any other aspect of this collection of including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency. 401 M Street, S.W., Washington, DC 20460. Do not to this address.

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le 04-30-99			EPA Reg No. File Symbol 69268- 2	. (0)	Page 1 of 1
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158.20 Efficacy	HIV Virucidal Test	44532003	Alphen, Inc.	own	69268- (
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ignature Kalla	-P192	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Name and Title  Kyle H. Sibinovic, Ph.O., Agent	h	04-30-99



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Form Approved, OMB No. 2070-0060

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Date 04-30-99	EPA Reg No. File Symbol 69268-		Page 1 of 1
Applicant's Registrant's Name & Address Alphen, Inc., A Div. of Dynachem P.O. Box 19 - Maple Grove Road, Georgetown, IL 61846	Product H <sub>2</sub> Orange <sub>2</sub> Concentrate 117		
Ingredient Hydrogen Peroxide	and the state of t	1 3 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	WAR A
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### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

### 01/21/00

### **MEMORANDUM**

Subject:

D258938

H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 EPA Registration No. 69268-2

From:

Wallace Powell, Biologist

Product Science Branch

Antimicrobials Division (7510C)

Thru:

Karen P. Hicks, Team Leader Chemistry/Toxicology Team

Product Science Branch

Antimicrobials Division (7510C)

Michele E. Wingfield, Chief Product Science Branch

Antimicrobials Division (7510C)

To:

Marshall Swindell, Product Manager, Team 33

Tony Kish, Team Reviewer, Team 33

Regulatory Management Branch Antimicrobials Division (7510C)

### **BACKGROUND**

The registrant, Alphen, Inc. (as represented by an agent), has submitted studies for primary eye irritation, primary dermal irritation, acute oral toxicity, and acute dermal toxicity – MRID Nos. 448926-01 through 448926-04, respectively. The studies were submitted in support of a registration amendment for H<sub>2</sub>Orange<sub>2</sub> Concentrate 117, EPA Registration No. 69268-2, a hard-surface treatment product containing hydrogen peroxide as the active ingredient at 3.95% of the formulation by weight. The registrant wishes to revise the human-hazard and practical-treatment statements on the product label and to change the Signal Word from DANGER to CAUTION. The submitted studies were initially reviewed for Product Science Branch (PSB) by Oak Ridge National Laboratory. The reviews are attached to this memorandum.

### RECOMMENDATION

The submitted studies are acceptable. PSB concurs with the acute Toxicity Categories listed below which were determined in the attached study reviews.

Acute effect	<u>Category</u>
Acute oral toxicity	III - LD <sub>50</sub> > 2000 mg/kg; this indicates Category III or IV.
•	Category III is assigned for regulatory purposes.
Acute dermal tox.	III - This limit test indicates Category III or IV. Category
	III is assigned for regulatory purposes.
Primary eye irritation	· III
Primary dermal irrit.	IV

The registrant selected  $\rm H_2Orange_2$  Super Concentrate 112 (EPA Registration No. 69268-1) as the test material for the dermal irritation, acute oral, and acute dermal toxicity studies. This is acceptable, since that product is more concentrated but otherwise similar to the subject product, and tested out to be non-irritating (Category IV) to the skin and only moderately acutely toxic (Category III) orally and dermally.

The above list of acute Toxicity Categories for the product is incomplete, lacking any reference to acute inhalation or dermal sensitization data or waivers. However, neither the EPA-accepted product label nor the new proposed label nor the registrant's 08/03/99 correspondence makes any reference to inhalation or sensitization. Therefore, the submitted studies are not being reviewed here as a proposed complete data set, but only as support for the label revisions.

### PRODUCT LABELING

The following comments apply, in regard to the proposed label of EPA Received date 08/06/99:

1. In the human hazards section, the registrant should delete the statement, "Product, after dilution according to directions, is non-irritating." The phrase "Undiluted product concentrate" should also be deleted from the statement, "Undiluted product concentrate causes moderate eye damage," because the phrase can be taken to imply that the use-dilution is harmless.

Even though the use-dilution proposed for sanitization is 1:32 by volume, the above text cannot be accepted in the absence of an eye irritation study on the dilution. The results of the submitted eye study on the concentrate are cause for concern. The reason that an eye irritation hazard level as mild as Category III can be assigned to the study is that the observed problems at Day 3 (72 hours) cleared before the Day 7 observation. The problems, however, were significant

and might have persisted at comparable levels for a considerable time after Day 3 (in the absence of further observations recorded before Day 7).

- 2. In the Practical Treatment section, the registrant should delete the phrase "with product concentrate" from the heading, "In case of CONTACT with product concentrate." No data were submitted or cited to support the concept that the use-dilutions need no practical-treatment statements. Category IV's would have to be assigned across-the-board in order for the full heading to be acceptable.
- 3. The statements required in the Agency's *Label Review Manual* for the humanhazards section are as follows:

Causes moderate eye irritation. Harmful if swallowed or absorbed through skin. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

Therefore, the following revision (at a minimum) is necessary:

Add the statement, "Harmful if swallowed or absorbed through skin."

4. The proposed "If swallowed" statements for practical treatment are not the statements indicated by the Agency's Label Review Manual for the proposed product. However, ingestion practical-treatment is a controversial topic, and the registrant's proposed statements can be accepted if the registrant considers them to be medically appropriate, and if the registrant adds to them an instruction to "call a physician or poison control center," or to "get medical attention."

### DATA EVALUATION REPORT

### HYDROGEN PEROXIDE

(ALPHEN H<sub>2</sub> ORANGE 2 SUPER CONCENTRATE 112)

STUDY TYPE: ACUTE ORAL TOXICITY - RAT (81-1) MRID 44892603; DP BARCODE: 258938

Prepared for

Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group Toxicology and Risk Analysis Section Life Sciences Division Oak Ridge National Laboratory Oak Ridge, TN 37831 Action No. K116

Primary Reviewer: Susan Chang, M.S.

Secondary Reviewers: H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

H. Tim Borges, M.1.(A.S.C.P.), Ph.D., D.A.B.

Robert H. Ross, M.S., Group Leader

Quality Assurance: Eric Lewis, M.S.

Signature:

Date:

Signature:

Date:

ıre:

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Signature:

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Signature:

Date:

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Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-960R22464.

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### HYDROGEN PEROXIDE

Acute Oral Study (81-1)

EPA	Reviewer:	Wallace	Powell,	Ph.D.

EPA Work Assignment Manager: Nader Elkassabany, Ph.D.

### DATA EVALUATION RECORD

STUDY TYPE:

Acute Oral Toxicity - Rat

OPPTS 870.1100 [§81-1]

DP BARCODE: D258938

P.C. CODE: 000595

SUBMISSION CODE: S567180

CASE NO.: 062401

TEST MATERIAL:

Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 (Hydrogen peroxide)

SYNONYMS: not reported

Graver, K. (1999) Acute oral toxicity/LD50 in rats. MB Research Laboratories, 1765 CITATION:

Wentz Road, P.O. Box 178, Spinnerstown, PA 18968. Research Project No. MB 99-

7513.01, June 25, 1999. MRID 44892603. Unpublished.

SPONSOR: Alphen, LLC, P.O. Box 19, Maple Grove Road, Georgetown, IL 61846

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 44892603) five male and five female fasted young adult Wistar rats per group were given a single oral 2000 mg/kg (Limit test) dose of Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 (Hydrogen peroxide, Batch No. 97334) by gavage and observed for 14 days.

No animals died during the study. Chromorrhinorhea, wet anogenital area, emaciation, few feces, nose/mouth area stained red, lethargy, flaccidity, ataxia, diarrhea, soiling of the anogenital area. and/or dyspnea were noted on some of the rats. All rats had normal body weight gains. Mottled kidneys were noted in two males and two females at necropsy.

The oral LD<sub>50</sub> for males, females, and combined was > 2000 mg/kg (Limit test).

Alphen H2 Orange 2 Super Concentrate 112 is in TOXICITY CATEGORY III based on the  $LD_{50}$ .

This acute oral study is classified as Acceptable/guideline and satisfies the Subdivision F guideline requirements for an acute oral study (81-1) in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

### I. MATERIALS AND METHODS

### A. MATERIALS

1. Test material: Alphen H<sub>2</sub> Orange 2 Super Concentrate 112

Description: clear light yellow liquid

Lot/Batch #: 97334 Specific gravity: 1.04 Composition: not reported

### 2. Vehicle and/or positive control

None

### 3. Test animals

Species: rat Strain: Wistar

Age and/or weight at dosing: approximately 7-13 weeks; males: 210-235 g, females:

212-233 g

Source: Ace Animals, Boyertown, PA Acclimation period: at least five days

Diet: fresh Purina Rat Chow No. 5012, ad libitum

Water: ad libitum

Housing: individually in suspended wire cages

Environmental conditions:
Temperature: not reported
Humidity: not reported
Air changes: not reported

Photoperiod: 12 hour light/dark

### B. STUDY DESIGN AND METHODS

### 1. In life dates

Start: April 23, 1999; end: May 7, 1999

### 2. Animal assignment and treatment

The study was conducted as a limit test. Following an overnight fast, five rats/sex were given a single 2000 mg/kg dose of the test material by gavage. The animals were observed for clinical signs of toxicity at 1, 2, and 4 hours post dosing and at least once daily for 14 days. Mortality was checked twice daily. They were weighed on study days 0, 7, and 14. All rats were sacrificed and necropsied.

TABLE 1. Doses, mortality/animals treated					
Dose (mg/kg)	Males	Females	Combined		
2000	0/5	0/5	0/10		

Data taken from p. 7, MRID 44892603.

### 3. Statistics

Calculation of the oral LD<sub>50</sub> was not required.

### II. RESULTS AND DISCUSSION

### A. MORTALITY

No animals died during the study.

The oral LD<sub>50</sub> for males, females, and combined was > 2000 mg/kg. This places Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 in TOXICITY CATEGORY III.

### **B. CLINICAL OBSERVATIONS**

Chromorrhinorhea was noted from three rats and wet anogenital areas were noted from four rats. Some of the rats had one or more of the following clinical signs: emaciation, few feces, nose/mouth area stained red, lethargy, flaccidity, ataxia, diarrhea, soiling of the anogenital area, and dyspnea. Two rats had no clinical signs during the study.

### C. BODY WEIGHT

All rats had normal body weight gains.

### D. NECROPSY

Mottled kidneys were noted in two males and two females. All other rats had normal necropsy.

### E. <u>DEFICIENCIES</u>

The temperature, humidity, and air change frequency of the animal room were not reported. These would not affect the study results.

### DATA EVALUATION REPORT

### HYDROGEN PEROXIDE (ALPHEN H<sub>2</sub> ORANGE 2 SUPER CONCENTRATE 112)

### STUDY TYPE: ACUTE DERMAL TOXICITY - RABBIT (81-2) MRID 44892604; DP BARCODE: 258938

Prepared for

Antimicrobials Division Office of Pesticide Programs U.S. Environmental Protection Agency 1921 Jefferson Davis Highway Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group Toxicology and Risk Analysis Section Life Sciences Division Oak Ridge National Laboratory Oak Ridge, TN 37831 Action No. K116

Primary Reviewer: Susan Chang, M.S.

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Robert H. Ross, M.S., Group Leader

Quality Assurance: Eric Lewis, M.S.

Signature:

Date:

Signature:

Date:

Signature:

Date:

Signature:

Date:

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

### HYDROGEN PEROXIDE

Acute Dermal Study (81-2)

EPA Reviewer: Wallace Powell, Ph.D.	Wolnell	, Date
EPA Work Assignment Manager: Nader Elkassabany	y, Ph <u>.D.</u>	, Date

### **DATA EVALUATION RECORD**

STUDY TYPE:

Acute Dermal Toxicity - Rabbit

OPPTS 870.1200 [§81-2]

DP BARCODE: D258938

SUBMISSION CODE: \$567180

P.C. CODE: 000595

CASE NO.: 062401

TEST MATERIAL:

Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 (Hydrogen peroxide)

SYNONYMS: not reported

CITATION: Cerven, D.R. (1999) Acute dermal toxicity in rabbits/LD 50 in rabbits. MB Research

Laboratories, 1765 Wentz Road, P.O. Box 178, Spinnerstown, PA 18968. Research Project No. MB 99-7513.02, June 22, 1999. MRID 44892604. Unpublished.

SPONSOR: Alphen, LLC, P.O. Box 19, Maple Grove Road, Georgetown, IL 61846

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 44892604) approximately 10% of the body surface area of five male and five female young adult New Zealand White rabbits was dermally exposed to 2000 mg/kg (Limit Test) Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 (Batch No. 97334) for 24 hours. The animals were observed for 14 days.

One male died within one hour of dosing. One female had few feces on day 6. No other clinical toxicity was noted during the study. Dermal irritation (erythema, edema, and/or flaking skin) was noted on all rabbits at 24 hours through day 14. Two surviving males failed to gain weight during the first week of the study. The body weight gains were normal for the other surviving rabbits. Gross necropsy revealed treated skin abnormalities on eight surviving rabbits.

The dermal LD<sub>50</sub> for males, females, and combined was > 2000 mg/kg (Limit Test).

Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 is in TOXICITY CATEGORY III based on the LD<sub>50</sub>.

This acute dermal study is classified as Acceptable/guideline and satisfies the Subdivision F guideline requirements for an acute dermal study (81-2)in the rabbit.

<u>COMPLIANCE</u>: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

### I. MATERIALS AND METHODS

### A. MATERIALS

1. Test material: Alphen H<sub>2</sub> Orange 2 Super Concentrate 112

Description: clear light yellow liquid

Lot/Batch #: 97334 Specific gravity: 1.04 Composition: not reported

### 2. Vehicle and/or positive control

None

### 3. Test animals

Species: rabbit

Strain: New Zealand White

Age and/or weight at dosing: approximately 12-15 weeks; males: 2.3-2.8 kg, females:

2.1-2.5 kg

Source: Ace Animals, Boyertown, PA Acclimation period: at least five days Diet: fresh Purina Rabbit Chow No. 5321

Water: ad libitum

Housing: individually in suspended wire cages

Environmental conditions:
Temperature: not reported
Humidity: not reported
Air changes: not reported

Photoperiod: 12 hour light/dark

### B. STUDY DESIGN AND METHODS

### In life dates

Start: May 5, 1999; end: May 19, 1999

### 2. Animal assignment and treatment

The study was conducted as a limit test using five male and five female rabbits. Animals were given a single 2000 mg/kg dose of Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 applied on top of a gauze patch (10x15 cm) to a clipped area (approximately 10% of the body surface) on the dorsal trunk. The trunk was wrapped with plastic which was secured with tape. The covering was removed 24 hours later and the site washed with distilled water. The test sites were scored for dermal irritation 24 hours after treatment

and on days 7 and 14. The animals were observed for clinical signs of toxicity 1, 2, and 4 hours postdose and once daily thereafter for 14 days. Mortality was checked twice daily. The animals were weighed prior to test material application, and on study days 7 and 14. All rabbits were sacrificed and necropsied.

#### 3. Statistics

Calculation of the dermal LD<sub>50</sub> was not required.

#### II. RESULTS AND DISCUSSION

#### A. MORTALITY

One male died within one hour of dosing.

The dermal LD<sub>50</sub> for males, females, and combined was > 2000 mg/kg. This places Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 in TOXICITY CATEGORY III.

#### **B. CLINICAL OBSERVATIONS**

One female had few feces on day 6. No other clinical toxicity was noted during the study. Very slight to moderate erythema was noted on all rabbits at 24 hours and day 7. By day 14, very slight erythema and moderate erythema were noted on one female and one male, respectively. Slight to severe edema was noted on all rabbits at 24 hours. Very slight and slight edema were noted on seven and one rabbits, respectively, by day 7. Two males had very slight edema by day 14. Flaking skin was noted on most of the rabbits by day 7 through day 14.

#### C. BODY WEIGHT

Two surviving males failed to gain weight during the first week of the study. The body weight gains were normal for the other surviving rabbits.

#### D. NECROPSY

Gross necropsy revealed treated skin abnormalities on eight surviving rabbits.

#### E. <u>DEFICIENCIES</u>

The temperature, humidity, and air change frequency of the animal room were not reported. These would not affect the study results.

#### DATA EVALUATION REPORT

## HYDROGEN PEROXIDE (ALPHEN H<sub>2</sub> ORANGE 2 SUPER CONCENTRATE 117)

#### STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT (81-4) MRID 44892601; DP BARCODE: 258938

Prepared for

Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group Toxicology and Risk Analysis Section Life Sciences Division Oak Ridge National Laboratory Oak Ridge, TN 37831 Action No. K116

Primary	Reviewer:
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Susan Chang, M.S.

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Robert H. Ross, M.S., Group Leader

**6** . W. . 4

Quality Assurance: Eric Lewis, M.A.

Signature:

Date:

Signature:

Date:

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#### Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

#### HYDROGEN PEROXIDE

Primary Eye Irritation Study (81-4) EPA Reviewer: Wallace Powell, Ph.D. EPA Work Assignment Manager: Nader Elkassabany, Ph.D.

#### DATA EVALUATION RECORD

STUDY TYPE:

Primary Eye Irritation - Rabbit

OPPTS 870.2400 [§81-4]

DP BARCODE: D258938

SUBMISSION CODE: S567180

P.C. CODE: 000595

CASE NO .: 062401

TEST MATERIAL:

Alphen H<sub>2</sub> Orange 2 Super Concentrate 117 (Hydrogen peroxide)

SYNONYMS: not reported

CITATION: Cerven, D.R. (1999) Acute eye irritation in rabbits. MB Research Laboratories, 1765

Wentz Road, P.O. Box 178, Spinnerstown, PA 18968. Research Project No. MB 98-

7280.04, February 22, 1999. MRID 44892601. Unpublished.

Alphen, LLC, P.O. Box 19, Maple Grove Road, Georgetown, IL 61846 SPONSOR:

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 44892601) 0.1 mL of Alphen H<sub>2</sub> Orange 2 Super Concentrate 117 (Batch No. 97297) was instilled into the conjunctival sac of three female New Zealand white rabbits. The contralateral eye of the rabbit served as control. The eyes were scored for ocular irritation according to the Draize method 1, 24, 48, and 72 hours after instillation and on day 7.

Corneal opacity was noted on 1/3 rabbits 24 hours after test material instillation and persisted through 72 hours before resolution by day 7. Iritis was noted on 3/3 rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbits by day 7. The test material induced conjunctival redness and chemosis one hour through 72 hours after test material instillation with resolution by day 7. Conjunctival discharge was noted on all rabbits one hour after test material instillation with resolution by day 7. The highest total ocular irritation index was 21.67 recorded 24 hours after test material instillation.

In this study, Alphen H2 Orange 2 Super Concentrate 117 was mildly irritating and is in TOXICITY CATEGORY III for primary eye irritation.

This study is classified as Acceptable/guideline and satisfies the Subdivision F guideline requirements for a primary eye irritation study (81-4) in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

#### I. MATERIALS AND METHODS

#### A. MATERIALS

1. Test material: Alphen H<sub>2</sub> Orange 2 Super Concentrate 117

Description: clear colorless liquid

Lot/Batch #: 97297

Composition: not reported

#### 2. Vehicle

None

#### 3. Test animals

Species: rabbit

Strain: New Zealand white

Age and weight at dosing: approximately 13-15 weeks; females: 2.0-2.4 kg

Source: Ace Animals, Boyertown, PA Acclimation period: at least five days. Diet: fresh Purina Rabbit Chow No. 5321

Water: ad libitum

Housing: individually in suspended cages

Environmental conditions:
Temperature: not reported
Humidity: not reported
Air changes: not reported
Photoperiod: 12 hour light/dark

#### B. <u>STUDY DESIGN AND METHODS</u>

#### 1. In life dates

Start: December 7, 1998; end: December 14, 1998

#### 2. Animal assignment and treatment

The test material (0.1 mL) was instilled into the conjunctival sac of three female rabbits and the eye lids held together briefly. The contralateral eye of each rabbit served as control. The treated eyes of the rabbits were examined with sodium fluorescein at 24, 48, and 72 hours and on day 7. The animals were scored for ocular irritation 1, 24, 48, and 72 hours after instillation and on day 7 according to the Draize method.

#### II. RESULTS AND DISCUSSION

A. Corneal opacity was noted on 1/3 rabbits 24 hours after test material instillation and persisted through 72 hours before resolution by day 7. Iritis was noted on 3/3 rabbits one hour after test material instillation with resolution on one rabbit by 48 hours and on two rabbits by day 7. The test material induced conjunctival redness (grade 1-3) and chemosis (grade 1-4) one hour through 72 hours after test material instillation with resolution by day 7. Conjunctival discharge was noted on all rabbits one hour after test material instillation with resolution by day 7. The highest total ocular irritation index was 21.67 recorded 24 hours after test material instillation.

This classifies the test material as mildly irritating. Alphen H<sub>2</sub> Orange 2 Super Concentrate 112 is in TOXICITY CATEGORY III.

#### **B. DEFICIENCIES**

The temperature, humidity, and air change frequency of the animal room were not reported. These would not affect the study results.

#### DATA EVALUATION REPORT

## HYDROGEN PEROXIDE (ALPHEN H<sub>2</sub> ORANGE<sub>2</sub> SUPER CONCENTRATE 112)

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT (81-5)

MRID 44892602; DP BARCODE: 258938

Prepared for

Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by

Chemical Hazard Evaluation Group Toxicology and Risk Analysis Section Life Sciences Division Oak Ridge National Laboratory Oak Ridge, TN 37831 Action No. K116

Primary	Reviewer:
Susan Cl	hang, M.S.

Secondary Reviewers:

H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Robert H. Ross, M.S., Group Leader

Quality Assurance: Eric Lewis, M.S. Signature:

Date:

Signature:

Date:

Signature:

Date:

Signature: Date: SEP 2 8 1999

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#### Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory, managed by Lockheed Martin Energy Research Corp. for the U.S. Department of Energy under contract number DE-AC05-96OR22464.

HYDROGEN PEROXIDE	Primary D	ermal Irritation Study (81-5
EPA Reviewer: Wallace Powell, PMD.	11 1/2 m/	, Date
EPA Work Assignment Manager: Nader Elkassaban	y, Ph.D	, Date

DATA EVALUATION RECORD

STUDY TYPE:

Primary Dermal Irritation - Rabbit OPPTS 870.2500 [§81-5]

DP BARCODE: D258938

SUBMISSION CODE: \$567180

P.C. CODE: 000595

CASE NO : 062401

TEST MATERIAL: Alphen H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 112 (Hydrogen peroxide)

**SYNONYMS**: not reported

CITATION:

Cerven, D.R. (1999) Acute dermal irritation in rabbits. MB Research Laboratories, 1765

Wentz Road, P.O. Box 178, Spinnerstown, PA 18968. Research Project No. MB 98-

7182.03, February 22, 1999. MRID 44892602. Unpublished.

SPONSOR:

Alphen, LLC, P.O. Box 19, Maple Grove Road, Georgetown, IL 61846

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 44892602) six female adult New Zealand white rabbits were dermally exposed on the dorsal trunk to 0.5 mL Alphen H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 112 (Batch No. 97293) for 4 hours. The animals were observed for 72 hours. Irritation was scored by the method of Draize.

No irritation was noted on any rabbit during the study.

In this study, Alphen H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 112 was not an irritant and is in TOXICITY CATEGORY IV for primary dermal irritation.

This study is classified as Acceptable/guideline and satisfies the Subdivision F guideline requirements for a primary dermal irritation study (81-5) in the rabbit.

<u>COMPLIANCE</u>: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

#### I. MATERIALS AND METHODS

#### A. MATERIALS

1. Test material: Alphen H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 112

Description: clear light yellow liquid

Lot/Batch #: 97293

Composition: not reported

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#### 2. Vehicle

None

#### 3. Test animals

Species: rabbit

Strain: New Zealand white

Age and weight at dosing: approximately 12-17 weeks; males: 2.6-2.9 kg, female: 2.8 kg

Source: Ace Animals, Boyertown, PA Acclimation period: at least 5 days

Diet: fresh Purina Rabbit Chow No. 5321

Water: ad libitum

Housing: individually in suspended wire cages

Environmental conditions:
Temperature: not reported
Humidity: not reported
Air changes: not reported
Photoperiod: 12 hour light/dark

#### **B. STUDY DESIGN AND METHODS**

#### 1. In life dates

Start: October 27, 1998; end: November 6, 1998

#### 2. Animal assignment and treatment

One female and two male animals were given a single 0.5 mL dose of Alphen H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 112 applied under a 2.5x2.5 cm gauze patch on the clipped dorsal trunk. The patch was secured with tape and the trunk was wrapped with plastic in a semi-occlusive manner. The dressings were left in place for 4 hours, after which they were removed and the application sites washed with distilled water. The site was scored for erythema and edema according to the Draize method 60 minutes, 24, 48, and 72 hours after patch removal.

#### II. RESULTS AND DISCUSSION

A. No irritation was noted on any rabbit during the study.

Alphen H<sub>2</sub> Orange<sub>2</sub> Super Concentrate 112 was not an irritant and is in TOXICITY CATEGORY IV.

#### B. <u>DEFICIENCIES</u>

The temperature, humidity, and air change frequency of the animal room were not reported. These would not affect the study results.

SUBMISSION BAR COL	DE # <u>\$56</u>	2)97	_ REVIEW	ver	-
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Alphen LLC P. O. Box 19 Maple Grove Road Georgetown, IL 61846

Mailed To:

Kyle Sibinovic, Agent For Alphen, Inc.

Shaldra, Inc.

4327 Reels Mill Road

Frederick, MD 21704-7759

RE:

EPA Reg. No. 69268-2

H<sub>2</sub>Orange, Concentrate 117 Your Notification Dated 4/30/99

The Notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to add a new supplier for the unregistered active ingredient, is unacceptable for the following reasons.

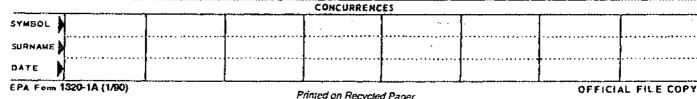
A. You must submit the request to add an additional unregistered source of active ingredient as a Amendment. As per PR Notice 98-10, Section III, "A registrant may NOT make the following active ingredient related changes by Notification, but must submit an application for Amendment: -A change to an unregistered source of an active ingredient". Include the following in this Amendment.

1. All unregistered sources of active ingredients need a generic data matrix. Therefore, when you submit your Amendment, you must submit a generic data matrix (white and blacked-out copy) for the additional source of hydrogen peroxide. This generic data matrix was not submitted for the original registration, and this was an oversight.

The original formulators Exemption Statement (FES) dated 4/6/98 and the one dated 4/30/99 do not apply, because the FES can only be used with registered sources of active ingredients. Item #2 on the FES clearly explains this restriction.

Even though the Peroxy RED waives all hydrogen peroxide generic data requirements, your matrix must list each guideline series listed in the RED for product chemistry, acute/subchronic/chronic toxicology, mutagenicity, ecological effects, fate, etc. You should insert the words "Waived in RED" in the "Submitter" column for each waived study.

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#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

- 2. To show that the new source of hydrogen peroxide is equivalent to the present source, you must submit or cite (on the generic data matrix), the following generic product chemistry studies completed on the additional source: 61-2 (Description of Production Process), 61-3 (Discussion of Impurities), 62-1 (Preliminary Analysis), and 62-2 (Certified Limits). For citations, you should include a copy of any original EPA review which found the study acceptable.
- 3. You must submit a revised Confidential Statement of Formula listing the name and address of the additional source of hydrogen peroxide.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443.

Marshall Swindell,

Product Manager Team 33.

Regulatory Management Branch I Antimicrobials Division (7510C)

	CONCURRENC	ES	
ZAWBOT			
SURNAME			
DATE			
EPA Form 1320-1A (1/90)	Printed on Decut		OFFICIAL FILE COPY

#### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Tony Kish
Registration Specialist
Antimicrobial Program Division (7510W)
US Environmental Protection Agency
Crystal Mall 2, Room 266A
1921 Jefferson Davis Hwy
Arlington, VA 22202

Re: Notification of additional supplier of active ingredient H₂Orange₂ Concentrate 117 EPA Reg. No. 69268-2 OPP ID# 233351 04-30-1999

Dear Mr. Kish:

Enclosed please find the following:

- Transmittal letter.
- Application for Pesticide Notification OPP ID # 233351.
- Certification with Respect to Citation of Data.
- Formulator's Exemption Form.
- 4. Copy of the MSDS for the new source of the hydorgen peroxide.

The active ingredient, hydrogen peroxide as supplied by the new source is in the same concentration as is the hydrogen peroxide source currently in use, and the additional source will not result in any change to the formula as given in the Confidential Statement of Formula currently on file with the EPA as part of the registration package for this product.

The sponsor believes that the addition of another source of hydrogen peroxide, the active ingredient in this product is a Notification under II. B. 1.

If you have questions regarding this submission, please contact Kyle H. Sibinovic, Ph.D. at the above telephone number.

Thank you for your attention to this submission.

Sincerely yours, Kashelman, Philo

Kyle H. Sibinovic, Ph.D. Agent for Alphen, LLC

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Please read instructions on reverse before completing form. Form Approved, OMB No. 2070-0060, Approvel expires 2-28-95
PEPA  Environmental Protection Agency  Amendment  Washington, Oc 20450  OPP Identifier Number  Amendment  OPP Identifier Number
Application for Pesticide Section Language Application for Pesticide Section for Pes
1. Company/Product Number 69268-2 2 EPA Product Manager 3. Proposed Classification Restricted
4. Company/Froduct, (Nama) 11. Orange 2 Conc
5. Name and Address of Applicant (Include ZIP Code)  Colliption Lic  (b)(i), my product is similar or identical in composition and labeling to:  You applied Review. In accordance with FIFRA Section 3(c)(3)  (b)(i), my product is similar or identical in composition and labeling to:  EPÄ Reg. No.  Check If this is a new address  Product Name
Section - III. The Control of the Co
Amendment Explain below.  Final printed lebels in response to Agency letter dated  Agency letter dated  Me Too Application  Notification Explain below.  Other Explain below.
The state of the s
Explanation: Use additional page (a) il necessary (For section I and Section II) AH, Hom a Herna Le abunca  Cert a Harried
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1. Material This Product Will Be Packaged In:
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1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application
Name Kyle H S. & Movie, Ph D Tille A Sex 10 801 895-1200
Certification  I comify that the statements I have made on this form and all attachments therefore true, accurate and complete.  Received  acknowledge that any knowingly false or misleading attachment may be publishable by fine of imprisonment of both under applicable law.
2. Signature . 3. Title Story or any story of the story o
4. Typed Name  Kyle N S. 18 1 novic PID  5. Date  14. 30 - 99  133
EPA Form 8570-1-[Rov. 8-94] Previous editions pro obsolute. White EPA File Copy. [Original] Voltow Applicant Copy

#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour pe response, including time for reviewing instructions, searching existing data pourous gethoring and maintaining the data needed, and completing and reviewing the collection of information. Send commente regarding the burden estimate of any other espect of the collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch; (2136), U.S. Environmental Protection Agency, 401 M Strast SW, Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budger, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to application far notifications, final printed labeling, reregistration, etc. In arder to process, an application for a how registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29) (III not exempted by 40 CFR 152.81 (b) (4)).
- 2. Confidential Statement of Formula (EPA Form 8570-4):
- 3. Formulator's Exemption Statement (EPA Form 8570-27);
- Five copies of dreft labeling;
- Three copies of any data submitted;
- Authorization latter where applicable;
- 7. Matrices where applicable.

Submission of Labeling. Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may in the form of typed label text on 8.5 x 11 inch paper for aubmission or a mockup of the proposed label. If prepared for mockup it should be: constructed in a way as to facilitate storage then 8.5 x 11 inch file. Mockup labels eignificantly emailer than 8.5 x 11 inches should be mounted on 8.5 k 11 inch paper for Submission. منيده بالم

Submission of Date - Date submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you era submitting this application, for applications submitted in connection with New Registration actions, Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, raregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

SECTION 1 - This section must be completed, as applicable; for all registration actions.

- 1. Company/Product Number Insert your Company Number, if and has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number
- EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification. Specify the proposed classification of this product.
- Product Name Enter the complete product name of this posticide as it will appear on the lebel. The name must be specific to this product only Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- Name and Address of Applicant The name of the firm or person endieddress shown in your application is the person or firm to whom the registration will be issued. If you are eating in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in ell. registration motters. The name and complete mailing address of such an agent must accompany this application.
- Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other posticide products that are currently registered with the EPA. In order for your application to be eligible for expedited raview, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II. This section must be completed for all applications submitted to amend the registration only of a currently registered product. (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA registered product. This section is not to be used for a new application for registration.

Subject of submission : Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purposets) for the submission, such as "the addition of a site, pestion grop (specify)"; amand the Confidential Statement of Formula by ... : "reregistration, submission"; "ganeral label revision of use directions.". Attach a separate paga il additional epaca is naeded.

SECTION III (Packating and Container Information). This Section must be completed for all epolications submitted in contaction is registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types Indicate the size of the individual packets and number per retail container.
- 2. Type Rotail Container Indicate type of container in which product will be marketed.
- 3. Socation of Net Contents Indicate the location of the net contents information for your product.
- Stanish of Ratell Coulding . Specify the nat contents of all ratell containers for your product!
- 5. Cognition of Use Directions Indicate the location of the use directions for your product
- 6. Magner in which lebel is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Contact Point) , This Section must be completed for all applications for Redistration actions, i.e., new products registration resubmission, "me too," reregistration, etc.

- 1-5. Self-explanatory:
- EPA Use Only.

#### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Re:

H2Orange2 Concentrate 117

EPA Reg. No. 69268-2

Notification of added active ingredient source and alternate brand name

OPP ID # 233351

This notification is consistant with the provisions of PR Notice 95-2 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 95-2 and 40 CFR 152.46, this product may be in ciolation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Sinned:

Kyle H. Sibinovic, Ph.D. Agent for Alphen, LLC Date: 04-30-1999

•: •: •:

Form Approved OMS No. 2070-0060



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.G., 20160							
Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for registration and special review activities, brefuding time for reading the instructions and completing the necessary forms. Send comments regarding blinden estimate or any other aspect of this collection of information, including suggestions for reducing the burden for Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W. Mashington, DC 20460.  Do not send the completed form to this address.							
Certification with Respec	t to Citation of	Data					
Applicant's Registrant's Name, Address, and Telephone Number Georgetown 16. EPA Registration Number/File Symbol Alphen. Div. of Dynachem. P.O. Box19-Haple Grove Rd. 301-695-1200 69268-12.							
Active Ingredient(s) and/or representative test compound(s)  Hydrogen Perbxide	·	Date 07-29-98					
General Use Pattern(s) (list all those claimed for this product using 40 CFR Pan 15 } Step degreaser, sanitizer, virucide and deodorizer for hard		Product Name HzOrangez Concentrate 117					
TE: If your product is a 100% repackaging of another purchased EPA-register striks form. You must submit the Formulator's Exemption Statement (EPA For		or affine same uses on your label, you do not need to					
i am responding to a Data-Call-In Notice, and have included with this form a be used for this purpose).	a list of companies s	ent offers of compensation (the Data Matrix form should					
SECTION I: METHOD OF DATA SUP	PORT (Check one n	nethod only)					
i am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	Under the	ig the selective method of support (or cite-all option e selective method), and have included with this form a id list of data requirements (the Data Matrix form must be					
SECTION II: GENERAL	OFFER TO PAY						
(Required if using the cite-all-method or when using the cite-all option under the sete							
SECTION III: CER	TIFICATION .						
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data in a would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.  I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study:							
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either; (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extend by sections 3(c)(1)(f) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.							
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(e)(1)(F) and/or 3(e)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce submit evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in ponforming with a FIFRA.							
I certify that the statements I have made on this form and all attache knowingly felse or misleading statement may be punishable by fine or impriso	nents to it are true, onment or both und	accurate, and complete. I acknowledge that any der applicable law.					
Signature Kyleddhow, PhD	Date 07-29-98	Typed or Printed Name and Title  Kylé H. Sibinovic, Phil, Agest					

EPA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

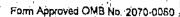


#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Corn Approved DMB No. 2070-0060

Paperwork Remidtion Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for registration activities activities activities activ

DATA MATE	RIX	
Date 07,729+98	EPA Reg No./File Symbol   69268-5, 2	Page 1 of 1
Applicant a Registratis Name & Address Alphen, Inc., A Div. of Dynachem P.O. Box 19 - Maple Grove Road, Georgetown, It, 61846	Product H <sub>2</sub> Orange <sub>2</sub> Concentrate 117	
Ingredient Hydrogent Reingxide		
Guideline Registered Number Guideline Study Name MRID N	umber Submitter	. Slalus . Note
	Alphen. Inc.	Own P Concentrate 112
	Alphen, Inc.	own : 69268-R
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Signature	Name and Title	Date
1 that I have the	Kyle H. Sibinovic, Ph.D., Agent	07-29-98
EPA Form 4570-35 (9-97) Electronic and Pager versions available Submit only Pager version.		Public File Copy





#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per reapolised for it reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other espect of this collection information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 2046d. Do not send the form to this address.

	DATA MATRIX		<u> </u>	
ale: ,		EPA Reg No!/File Symbol 69268-6		Page 1 of 1
pplicant's Registrant's Name & Address Alphen Inc., A Div. of Dynachem P.O. Box 19- Maple Grove Road, Georgetown, IL 618	46	Product: H2 Orange2 Concentrate	17 (3)	
igradiant Hydrogen Reroxtde	, , , , , , , , , , , , , , , , , , , ,	<u>- </u>		
uideline Reference Number Guideline Study Name	MRID Number	Submitter	Status	Note
158.20 81+11to 3 Product Chemistry	44532001	Alphen, Inc	own:	Hz Orangez Su Concentrate 1
158.20 62-1 to 3 Product Chemistry	44532001	Alphen, Inc	own	69268-R
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: 158.20 Effficacy AOAC Sanitizer Test	44532002	Alphen, inc.	own	69268-R
158-20 Efficacy HIV Virucidal Test	44532003	Alphen, Inc.	own	1 69268-R
158.20 Efficacy Virucidal Effectiveness	44560101	Alphen, inc.	own	69258-R
158.20 61-1 to 3. Product Chemistry	44582301	Alphen, Inc.	own	69268-E
158.20 62-1 to 3 Product Chemistry	44582301	Alphen lnc.	own	69268-E
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Ignature Colon Disp		Name and Title  Kyle H. Sibinovic, Ph.D., Ager	o <b>t</b>	Dado 07-29-98

United States Environmental Protection Agency
Washington, DC 20460

	(40 CFR 152.85	la Symbol/Registration Number 3
Applicant's Name and Address		JSPS-T
Alphan, Lle	s	Name
Robor 19 Maple Gare Rd George trum, IL 61	Freedo	Drange 2 Concentrate 117
maple give Yd	7	f Confidential Statement of Formula IEPA Form 8570-
Gener town II - in	No Cif	on I and OO
	3 12	04-06-98
As an authorized representative of th	ne applicant for registration of the prod	luct identified above, I here certify that:
(1) This product contains the follo	wing active ingredient(s):	*
Hydroge Pe	rupide	
· .	ient listed in paragraph (A) is present s	
(3) Indicate by checking (A) or (B	tatement of Formula (EPA Form 8570	4) for the above identified product is
product name, the source of the (B) The Confidential Statement is complete, current, and accu	he active ingredient(s) listed in paragra  OR	referenced above and on file with the EPA ired on the current CSF.
product name, the source of the (B) The Confidential Statement is complete, current, and accu	he active ingredient(s) listed in paragra OR t of Formula (CSF) (EPA Form 8570-4) trate and contans the information requi	ph (1).  I referenced above and on file with the EPA ired on the current CSF.
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Product name, the source of the product name, the source of the product name, the source of the product ingredient that the product ingredient source in the product in the	he active ingredient(s) listed in paragra OR t of Formula (CSF) (EPA Form 8570-4) trate and contans the information requients in this product qualify for the form  Product Name	referenced above and on file with the EPA ired on the current CSF.  ulator's exemption.  Source  Registration Number

### Paperwork Reduction Act Notice

The public reporting burden for this collection of information is estimated to average 1.5 hours per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Chief, Information Policy Branch, PM-223 U.S. Environmental Protection Agency 401 M Street, S.W. Washington, DC 20460

and to

Office of Management and Budget Paperwork Reduction Project (2070-0060) Washington, DC 20503

<b>J</b>	Product ingredient	cos. cooman	ay 20 onuic	a is oomiasiina	

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CODING FORM FOR A	PPLICAT	IONS FOR	REGISTR	ATION/AMI	ENDMENTS
FILE SYMBOL/REG NO. 6 DESCRIPTOR Final	g 268- printeb	2 pm 3 labels	AC	TION CODE_	302
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REGISTRATION TYPE	: - [ ] C	DNDITIONAL	[ ]	UNCONDITIO	NAL .
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RESPONSE CODE	38/	RI	esponse d	ATE MAY 2	7 1999

Alphen LLC P. O. Box 19 Maple Grove Road Georgetown, IL 61846

Mailed To:

Kyle Sibinovic, Agent For Alphen, Inc.

Shaldra, Inc.

4327 Reels Mill Road

Frederick, MD 21704-7759

RE:

EPA Reg. No. 69268-2

H. Orange, Concentrate 117

Your Submission Dated 4/8/99 Containing Final Printed Labels

This will acknowledge receipt of your final printed labels for H, Orange, Concentrate 117, which were attached to your letter dated 4/8/99. The submitted final printed labels have been placed in your product file. They have neither been reviewed nor stamped in accordance with the PR Notice 82-2.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443.

Sincerely,

Marshall Swindell,

Product Manager Team 33,

Regulatory Management Branch I

Antimicrobials Division (7510C)

KZ CONCURRENCES SYMBOL SURNAME DATE EPA Form 1320-1A (1/90) OFFICIAL FILE COPY

Printed on Recycled Paper



Alphen: 800-281-9604

#### **DIRECTIONS FOR USE**

it is violation of Federal law to use this product in a manner inconsistent with its labeling.

Alphen H<sub>2</sub>Orange<sub>2</sub> 117, when used as directed as a sanitizer, kills 99.99% or more of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebstella pneumoniae, Pseudomonas aenulnosa, Streptococcus recells, and Escherichia coli. When used as directed as a virucida. Alphen H2Orange2 117 kills the following viruses in 5 minutes or less at room temperature (204-10C). Herpes simplex virus Type 2, influenza A2/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral egents are killed as stated, use 10 oz. of product concentrate per gallon of water.

1-STEP CLEANING AND SANITIZING: Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily,

TO USE AS A SANITIZER AND VIRUCIDE IN BATHROOMS: Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily.

TO USE AS A SANSMIZER AND VIRUCIDE ON INANIMATE, MARD, NON-POROUS SURFACES: Add 10 ounces of product concentrate per gellion of water Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to eir dry or wipe dry to remove excess liquid. Heavily solled surfaces should be precleaned with the same solution. Replace solution daily.

MIN: To will KIV in 5 minutes at room temperature (20-250 C) on precisaned environmental surfaces/objects previously solled with blood/body fluids at a concentration of 1 027 gallon (1 part of Alphen H2Oranga2 117 to 127 parts of water). For use in health care settings or other settings in which there is an expectate theilhood of soiling of manimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be solidd with blood or body fullds can be associated with the potential for transmission of human immunodeliciancy virus Type I (HiV-1 Associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings.

Cleaning Procedure: Slood and other body fluids must be thoroughly cleaned from surfaces and objects before application of diluted product using

the Heavy or Super Duty Cleaning Solution.

Contact time: While the HiV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard. water (up to 400 phil hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officer.

#### DEODORIZING

For general deodorizing, use 2 part Alphen H2Orange2 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts Alphen H2Orange2 117 to 118 (10 oz / gallon) parts water. Apply to hard, non -porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-fleostomy, dressing end bag changes, and other spills such as urine or lecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

CLEANING SOLUTION DILUTIONS & APPLICATIONS (Display with Alphenis Dispensing System Only)

LIGHT DUTY (1 Oz / gal)GREEN (bonte or label) Streak free window, mirror and stainless steel cleaning General floor cleaner for mopping & auto scrubbers Bonnet cleaning solution for carpets Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gal) BLUE (boitle or label) General wipe down cleaner Mopping solution for Bathroom and Kitchen floors General carpet spot remover

**HEAVY DUTY** (10 Oz / gal) RED (bottle or label) Bathroom, shower room, tile & grout cleaner Urine and garbage odor eliminator Pre-spray for carpet extraction General degreeser Heavy soil wipe down cleaner Heavy carpet spot remover Cleans Mold & mildew

SUPER DUTY (24:48 Oz / gal) PURPLE (bottle or label) Renovation of tite & grout surfaces Oifficult urine & garbage odor destruction Scuff marks and stubborn stains Cleans heavy mold & miktew

Alphen: 800-281-9604

## PRECAUTIONARY STATEMENTS HAZARDS TO HUMAN AND DOMESTIC ANIMALS

**DANGER.** Undiluted product concentrate may cause severe eye damage. Do not get in eyes, on skin or clothing. Wear safety glasses or other eye protection and rubber gloves when handling concentrate. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing-before reuse.

After product leadiluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.

#### STATEMENT OF PRACTICAL TREATMENT

\*hrease of CONTACT with product concentrate

If In eyes: Flush immediately with cold water. Remove contact lenses. Continue flushing for 15 minutes,

\* frolding eyelids apart. Get prompt medical attention.

If on skin: Immediately wash with plenty of soap and water. Get medical attention.

If swallowed: Promptly drink large quantity of water. Avoid alcohol. Do not induce vomiting. Never give anything by mount to an unconscious person.

#### STORAGE AND DISPOSAL

IN CASE OF SPILL: Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

STORAGE: Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 950F Best storage temperatures are between 350F and 850F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL:** Completely empty container. Do not reuse empty containers. Leave empty plastic bag in original box and discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.



## **CONCENTRATE 117**

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD. CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES

ACTIVE INGREDIENT
Hydrogen peroxide
3.95%

OTHER INGREDIENTS
96.05%

TOTHAL
100.00 %

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS
SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 069268-2 EPA Est. No. 069268-IL-001

> ALPHEN, INC. MAPLE GROVE ROAD GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

NOT REVIEWED
In Accordance with PR Notice 82-2.
Based on Draft Labeling Dated

#### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Tony Kish
Registration Specialist
Antimicrobial Program Division (7510W)
US Environmental Protection Agency
Crystal Mall 2, Room 266A
1921 Jefferson Davis Hwy
Arlington, VA 22202

Re: submission Final Printed Labels H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 EPA Reg. No. 69268-2 OPP ID# 233346 04-08-1999

Dear Mr. Kish:

Enclosed please find the required copies of the final printed label for the above referenced product, H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 (EPA Reg. No. 69268-2), for inclusion in the product file.

The sponsor, Alphen LLC, wishes to thank you for all your help and assistance with this project, your advice and availibility are greatly appreciated.

Sincerely yours,
Klessellen 122

Kyle H. Sibinovic, Ph.D. Agent for Alphen, LLC

Please read instructions on reverse before completing form.	Form Approved. OMB No. 207	Q-0060. Approvel expires 2-28-95			
SEPA Environmental Protection Age Weshington, DC 20460	Other				
	esticide - Section I				
1. Company/Product Number 69268-3	2. EPA Product Manager	3. Proposed Classification			
4. Company/Product (Name) Ha Drawage & Discussions		The second secon			
5. Name and Address of Applicant Minclude ZIP Code)  Pobex 19 maple growth  George town IL 61846	6. Expedited Review. In accordance (b)(i) my product is similar or identica to:				
Check if this is a new address	Product Name				
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Amendment - Explain below.  Rasubmission in response to Agency letter dated  Notification - Explain below.	Final printed labels in response to Agency letter dated "Me-Too" Application	03102 99			
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Explanation: Use additional page(s) if necessary. (For section land Section II)					
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1. Material This Product Will Be Packaged In	を 10mm 10mm 10mm 10mm 10mm 10mm 10mm 10m	No. 1 . The Control of the Control			
Ves No	No. s Service of the	ntainer Aétal Instic			
Pertification must Unit Packaging wgt. Container Packaging wgt.	2 10 00	aper Other (Specify)			
3. Location of Net Contents Information 4. Size(s) Retail Conteiner	On Labela				
8. Manner in Which Label is Affixed to Product Paper glued Stenciled;	Other State of the				
Section - IV. Land Section - IV. Land Control of the section - IV. Land Control of the section - IV.					
1. Contact Point  Complete items directly below for identification of indiv	lual to be contacted, if necessary, to proce	ss this application.)			
Name Kyle HSIBINOVIE PhD Tillo	following the transfer in the contract of the	ephone No. (Include Aree Code)			
Certification I certify that the statements I have made on this form and all attach I acknowledge that any knowingly false or misleading statement ma both under applicable law.		6 Date Application Received  (Stamped)			
2. Signatura School Sch	A second				
4. Typed Name  Kyle H Signovic Phil	04/08/98	157			

#### PAPERWORK REDUCTION ACT, NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is actimated to average 0.85 hour per response, including time for reviewing instructions, coarching existing date courses, gethering and meintaining the date needed, and completing and reviewing the collection of information. Send completing end reviewing the collection of information, including a suggestions for reducing this burden, to Chief, information Policy Branch (2136); U.S. Environmental Protection Agency, 401 M. Street, SW. Washington, DC 20460; and to the Office of Information and Regulatory Affairs Office of Management and Budget, Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use reregistration, emandment resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

- 1. Certification with Respect to Citation of Data (EPA Form 8570-29). Ill not exempted by 40 CFR 152.81 (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3 Formulator's Exemption Statement (EPA Form 8570-27):
- 4 Five copies of draft labeling;
- 5. Three copies of any date submitted;
- 6 Authorization letter where explicable;
- 7. Matrices where applicable.

Submission of Labeling - Lebeling should first be submitted in the form of greft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If proposed for mockup, it should be constructed in a way as to facilitate storage in an 8:5 x 11 inch file Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 1

Submission of Data - Date submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed bolow before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, atc., Sections I, II, and IV must be completed by the applicant.

Block A. Check the appropriate action for which you are submitting this form.

SECTION | This section must be completed, as applicable, for all registration actions.

- Company/Product Number lisert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrent, a distributor, or as an establishment. If your product is registered, insert the Product Number,
- 2. EPA Product Manager II known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- 4) Product Name Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only.

  -Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- 5. Name and Address of Applicant: The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- 6. Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration or amendments to existing registration that are similar or identical to other pasticide products that are currently registered with the EPA. In order for your epplication to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II. This section must be completed for all applications submitted to smand the registration only of a currently registered product.

(Amendment), for a resubmission in response to an Agency letter; for notifications to the Agency, for the submission of final printed labeling, for resugnitivation and for any other action that parteins to a specific EPA registered product. This section is not to be used for a new application for registration.

1. Subject of submission. Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, peet or grop (specify)." Tamend the Confidential Statement of Formula by..." Transplatement of submission." "General label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Peckaging and Container Information). This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types
- 2. Type of Retail Container Indicate type of container in which product will be marketed.
- 3. Exceptor of Net Coments, Indicate the location of the nat, contants information for your product.
- 4. Sixes of Retail Container Specify the nat contents of all retail containers for your product.
- 5. Localism of Use Descrions Indicate the location of the use directions for your product.
- 6. Manager in which label is attixed to product. Indicated the mothod product label is attached to retail container

SECTION IV (Contradition) - This Section must be completed for all applications for Registration actions, i.e., new products registration resubmission, "me-tea," reregistration, etc.

- 1-5. Self-explenatory.
- 6. EPA Use Only.

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RESPONSE CODE \_\_/8

RESPONSE DATE MAR 0 2 1999



#### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (H7505C)

"M" \$L, S,W.

Washington, D.C. 20460

EPA Reg. Number:

Date of Issuance:

69268-2

MAR 0 2 1999

Term of Issuance:

CONDITIONAL

Name of Pesticide Product:

H,ORANGE, CONCENTRATE 117

\_\_ Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

NOTICE OF PESTICIDE: x Registration

Alphen, Inc.

Division of Dynachem

P.O. Box 19, Maple Grove Road

Georgetown, IL 61846

Nute: Changes in labeling differing in substance from that accepted in connection with this registration, must be submitted to and accepted by the Registration Division prior to use of the label incommerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named posticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a positicide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for re-registration of your product under FIFRA section 4.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

The condition of registration included in the original Notice of Registration dated 9/10/98, requiring the submittal of additional efficacy data has been satisfied. This new Notice is being issued to remove the original automatic expiration date imposed upon this registration.

Signature of Approving Official:

Marshall Swindell

Product Manager 33

Regulatory Management Branch 1 Antimicrobial Division (7510W)

MAR 0 2 1999

page 2 EPA Reg. No. 69268-2

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Tony Kish at (703) 308-9443.

Sincerely,

Marshall Swindell

Product Manager 33

Regulatory Management Branch 1 Antimicrobial Division (7510W)

Enclosure

(logo)

H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-POROUS SURFACES

ACTIVE INGREDIENT Hydrogen peroxide

3.95%

OTHER INGREDIENTS

96.05%

TOTAL

100.00 %

ACCEPTED with COMMENTS in EPA Letter Dated:

KEEP OUT OF REACH OF CHILDREN

DANGER

PRECAUTIONARY STATEMENTS

MAR 0 2 1999
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

69268-2

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 069268-2 EPA Est. No. 069268-IL-001

> ALPHEN, INC. MAPLE GROVE ROAD GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the buman body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact inuceus membranes; but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

#### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMAN AND DOMESTIC ANIMALS

Danger. Undiluted product concentrate may cause severe eye damage. Do not get in eyes, on skin or clothing. Wear safety glasses or other eye protection and rubber gloves when handling concentrate. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.

#### STATEMENT OF PRACTICAL TREATMENT

in case of CONTACT with product concentrate

If in eyes: Flush immediately flush with cold water. Remove contact lenses. Continue flushing for 15 minutes, holding eyelids apart. Get prompt medical attention.

If on skin: Immediately wash with plenty of soap and water. Get medical attention.

If swallowed; Promptly drink large quantity of water. Avoid alcohol. Do not induce vomiting. Never give anything by mouth to an unconsious person.

#### STORAGE AND DISPOSAL .....

IN CASE OF SPILL: Clean up immediately. Place leaking container in well ventilated area. To clean up spill,—flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

STORAGE: Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL**: Completely empty container. Do not reuse empty containers. Leave empty plastic bag in original box and discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.

ACCEPTED with COMMENTS in EPA Letter Dated:	
MAR 0 2 1532 Under the Federal Insecticide, Pungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 69268-2	

#### DIRECTIONS FOR USE

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

Alphen 117, when used as directed as a sanitizer, kills 99.99% or more of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruinosa, Streptococcus faecalis, and Escherichia coli. When used as directed as a virucide, Alphen 117 kills the following viruses in 5 minutes or less at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

1-Step Cleaning and Sanitizing: Using the appropriate cleaning solution for the type of surface to be treated, thorounly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

To use as a sanitizer and virucide in bathrooms: Add 10 oz. of product concentrate per gallon of water for sinks, taucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily.

To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces: Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

HIV: To kill HIV in 5 minutes at room temperature (20-25° C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of Alphen 117 to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned form surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officier.

Deodorizing

For general deodorizing, use 2 part Alphen 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts Alphen 117 to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

ACCEPTED with COMMENTS in EPA Letter Dated:

MAR 0 2 1999

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

69268-2

16Y

#### **CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute with Alphen's Dispensing System Only)

LIGHT DUTY (1 Oz / gal)GREEN (bottle or label)
Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)
General wipe down cleaner
Mopping solution for Bathroom and Kitchen floors
General carpet spot remover

HEAVY DUTY (10 Oz / gal) RED (bottle or label)
Bathroom, shower room, tile & grout cleaner
Urine and garbage odor eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew

SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)
Renovation of tile & grout surfaces
Difficult urine & garbage odor destruction
Scuff marks and stubborn stains
Cleans heavy mold & mildew

ACCEPTED with COMMENTS in EPA Letter Dated:

MAR 0 2 1999
Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
6 9 2 6 8 - 2

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#### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Tony Kish
Registration Specialist
Antimicrobial Program Division (7510W)
US Environmental Protection Agency
Crystal Mall 2, Room 266A
1921 Jefferson Davis Hwy
Arlington, VA 22202

09-02-1998

Re:Application for Pesticide Registration: H<sub>2</sub>Orange<sub>2</sub> Concentrate 112 - EPA File Symbol; 69268-R Response to EPA verbal request for data of 08-31-98 OPP ID # 233332

Dear Mr. Kish:

As suggested by Mr. Swindell, this letter is directed to you rather than to Mr. Swindell as you row have all the information on both of the Alphen, Inc. Products. In response to conversations between you, and/or Marshall Swindell and myself (08-31-1998), we are providing the following:

1. Transmittal letter.

Application for Pesticide Registration Form (OPP ID #233332.)

Required Certification with Respect to Citation of Data using the new form.

- 4. Three copies of Volume 1 Product Chemistry H₂Orange₂ Concentrate 112 -An Oxidizing Multipurpose, 1 Step Cleaner, Degreaser, Sanitizer (Non-Food Contact Surfaces, Virucide, & Decorrizer for Hard Surfaces Revised Sections 61-3, and 63-17, & Section on Identity, Strength, and Purity of Product used in Efficacy Testing. (Raw Data)
- Three copies of Volume 2 AOAC Sanitizer Test (for non-food contact surfaces) for Hiphen Product 112 Raw Data (LPI# Alphen 97-10, Presque Isle Cultures).
- Three copies of Volume 3 Virucidal Efficacy Testing of Alphen, L.L.C.'s Product 110 Against the Human Immunodeficiency Virus (HIV-1).- Raw Data (LPI# 9268.0, Southern Research)

7. Three copies of Volume 4 - Virucidal Effectiveness Test - Raw Data (LP⊯ 391-102, Microbiotest)

As instructed, at this time no new labels are included. However, the sponsor will change the signal word to Danger until such time as testing of the above product warrents a change in signal word. At such time as the label review is completed, we will, of course, submit as needed the final labels.

Please let me know directly if you have additional questions regarding this product. Alphen is a very small company and is very anxious to have the registration of the products with at least conditional registrations so that they can introduce them at the Fall meeting of the National group that sponsors these types of products. Any assistance that you can give us would be greatly appreciated.

I would appreciate it if you would call me as soon as possible regarding the status of this product so that I can pick up the response letter.

Thank you for your assistance with this Application.

Sincerety yours, Kseth Schonores, PhD

Kyle H. Sibinovic, Ph.D. Agent for Alphen, Inc.

#### TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER

Alphen Inc. P.O. Box 19 Georgetown, IL 61846

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUPPLYED

#### DATE RECEIVED BY EPA

#### LIST OF SUBMITTED STUDIES:

Volume 1: H2 Orangez Super Concentrate 112-An Oxidizing Multipurpose, 1-Step Chaner, Degreaser, Sanitizer. MRID: 44646001

Volume 2: ACAC Sanitizer Fest (For Non Food Contact Surfaces)

For Alphin Product 112.

MRID: 44646002

Volume 3: Virucidal Efficacy Testing of Alphen, L.L.C's -Product 110 Against the Human Immunadeficiency Virus (HIV-1). MRID: 44646003:

Volume 4: Viral Effectiveness Test. MRID: 44646004

#### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

ALPHEN, INC. P.O. BOX 19 GEORGETOWN, IL 61846

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 09/03/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

### **MEMO**

To:

Marshall Swindell, PM 33

From:

Tony Kish

RE:

69268-2 Raw Data Submitted to Front

End

Date:

11/9/98

Kyle Sibinovic submitted the raw data, as required in the time limited registration, to the front end and it was date stamped 9/3/98, and given MRID 446460-01 (product chemistry), -02 (sanitizer test), -03 (HIV), and -04 (viruses) Do you have it? We need to log in and send to Srini ASAP as the one year registration clock is ticking (to give them time to contract a study in case we reject any data).

& Surapt page

#### 202.0 Recommendations:

### 202.1 Raw data acceptable:

- 1-Reviewed raw data of all three studies and appeared to be acceptable except for the last virucide study against Polio virus II (VR-61) in which the test product failed. However, this virucide activity against polio virus is not claimed on the label.
- 2- Previous efficacy review recommendations concerning label corrections have not been amended.

#### EFFICACY AND SCIENCE SUPPORT BRANCH

#### ANTIMICROBIAL DIVISION

#### **EFFICACY REVIEW - I**

In:

10/19/98

Out:

January 14, 1998

Reviewed by:

Ibrahim Barsoum

Date: January 13, 1998

EPA Reg. No.:

69268-1

DP Barcode:

D250216

EPA Petition No.:

none

MODICE INGREDIENT SOUTH A DECALEMENT IS NOT INTELLIBED

Date Division Received:

9/4/98

Type Product:

Cleaner, Sanitizer, Virucide, and deodorizer

MRID No.:

44646-1, 44646-2, 44646-3, 44646-4

Product Manager:

Marshall Swindell

PM Team Reviewer:

Tony Kish

Product Name:

H2 Orange2 Super Concentrate 112

Company Name:

Alphen, Inc.

Submission Purpose:

Submission of raw data of previously submitted efficacy data.

Type Formulation:

Liquid

**Active Ingredients:** 

Hydrogen Peroxide

... 7.95%

PRODUCT INCREDIENT SOURCE INFORMATION IS NOT INCLUDED

#### RISK ASSESSMENT AND SCIENCE SUPPORT BRANCH

#### ANTIMICROBIAL DIVISION

#### **EFFICACY REVIEW - II**

EPA Reg. No.:

69268-1

DP Barcode:

D250216

EPA Petition No.:

none

Date Division Received:

9/4/98

Type Product:

Cleaner, Sanitizer, Virucide, and deodorizer

MRID No.:

44646-1, 44646-2, 44646-3, 44646-4

Product Manager:

Marshall Swindell

PM Team Reviewer:

Tony Kish

Product Name:

H2 Orange2 Super Concentrate 112

Company Name:

Alphen, Inc.

200.0 Introduction:

200.1 Uses:

200.2 Background Information: Raw data of previously submitted efficacy results.

201.0 Data Summary: None

201.1 Abstract of Test Reports: None

#### 201.2 Brief Description of Test:

Raw data are provided to support the efficacy of the product as a non-food contact Sanitizer and as a Virucide. Characterization data (identity, purity, strength, and composition of test substances) to verify that the efficacy data were developed at the proper concentrations are also provided.

201.3 Data Summaries: None

#### 201.4 Other Summarized Results:

See Recommendations under 202.0.

#### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Tony Kish Registration Specialist Antimicrobial Program Division (7510W) **US Environmental Protection Agency** Crystal Mail 2, Room 266A 1921 Jefferson Davis Hwy Artington, VA 22202

09-02-1998

Re:Application for Pesticide Registration: H, Orange, Concentrate 112 - EPA File Symbol: 69268-R Response to EPA verbal request for data of 08-31-98 OPP ID # 233332

Dear Mr. Kish:

As suggested by Mr. Swindell, this letter is directed to you rather than to Mr. Swindell as you now have all the information on both of the Alphen, Inc. Products. In response to conversations between you, and/or Marshall Swindell and myself (08-31-1998), we are providing the following:

Transmittal letter. 1.

Application for Pesticide Registration Form (OPP ID #233332.) 2.

Required Certification with Respect to Citation of Data using the new form. 3.

Three copies of Volume 1 - Product Chemistry - H₂Orange₂ Concentrate 112 -An Oxidizing Multipurpose, 1-4. Step Cleaner, Degreaser, Sanitizer (Non-Food Contact Surfaces, Virucide, & Decourizer for Hard Surfaces -Revised Sections 61-3, and 63-17, & Section on Identity, Strength, and Purity of Product used in Efficacy Testing. (Raw Data)

5. Three copies of Volume 2 - AOAC Sanitizer Test (for non-food contact surfaces) for Alphen Product 112 - Raw

Data (LPI# Alphen 97-10, Presque Isle Cultures).

Three copies of Volume 3 - Virucidal Efficacy Testing of Alphen, L.L.C.'s Product 110 Against the Human Immunodeficiency Virus (HIV-1) - Raw Data (LPI# 9268.0, Southern Research) 6.

7. Three copies of Volume 4 - Virucidal Effectiveness Test - Raw Data (LPI# 391-102, Microbiotest)

As instructed, at this time no new labels are included. However, the sponsor will change the signal word to Danger until such time as testing of the above product warrents a change in signal word. At such time as the label review is completed, we will, of course, submit as needed the final labels.

Please let me know directly if you have additional questions regarding this product. Alphen is a very small company and is very anxious to have the registration of the products with at least conditional registrations so that they can introduce them at the Fall meeting of the National group that sponsors these types of products. Any assistance that you can give us would be greatly appreciated.

I would appreciate it if you would call me as soon as possible regarding the status of this product so that I can pick up the response letter.

Thank you for your assistance with this Application.

Sincerely yours,

KRAS Kyle H. Sibinovic, Ph.D.

Agent for Alphen, Inc.

This Row data was Regined by the Reg. Notice dated 9/10/98. It is leving reviewed unelor 69268- A formal employ to 69268- Dalos. See \$550002)

Tony (12)

Alphan Inc. P.O. Box 19 Georgetown, IL 61846

#### DATE RECEIVED BY EPA

### LIST OF SUBMITTED STUDIES:

Volume 1: Hz Orangez Siper Concentrate 112-An Oxidizing Multipurpose, 1-step Chaner, Degreaser, Sanitizer MRID: 44646001

Volume 2: ACAC Sanitizer Test (For Non Food Contact Surfaces) for Alphin freduct 112.

MRID: 44646002

Volume 3: Virucidal Etticacy Testing of Alphon, L.L.C's. Product 110 Against the Human Immunadeticioney VITUS (HIV-1). MRID: 44646003:

10 lune 4: Viral EHectiveness Test. MRID: 44646004

#### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

ALPHEN, INC. P.O. BOX 19 GEORGETOWN, IL 61846

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/30/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected study [01] :

\* When data confidentiality is claimed under FIFRA Section 10 (d)(1)(A), (B), or (C), all confidential information must be excised from the body of the study and placed in a Confidential Attachment. See pages 8 and 15 of PR Notice 86-5.

DISREGARD THIS SUBMISSION SUBMISSION BAR CODE #5550000 REVIEWER THISH

[ ] CHILD RESISTAN	T PACKAG	ING: [ ] [ ] [ ]	CERTIFIC NON-RESI NOT APPL	DENTIAL USE OF	NLY
REGISTRATION TYPE:	- [ ] C	LANOITIONAL	[ ]	UNCONDITIONAL	,
PROPOSED CLASSIFIC	CATION:	[ ] GENER	AL [ ]	RESTRICTED US	E
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FISH/WILDLIFE			1		
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STATUS					•

This is an ACCEPTED submission.

One copy of the PPC diagnosis and one copy of the annotated bibliography are: provided for your files. The PPC has already mailed out the submitter's copies of the two documents.

This is a PARTIALLY ACCEPTED A COMPLETELY PLETS THE COMPLETELY PLETS THE PROPERTY.

A regy of the PPD pregress and the snhormed bibliography are provided for jour files. A second copy is provided for your use in corresponding with the com-

Send New CSF+ label to Cham

Herry He csf and seak will deep purlage to being show that

N9

ed States ironmental Protection ncy shington, DC 20460

ial Business illy for Private Use



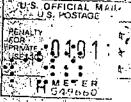
United States Environmental Protection Agency Washington, DC 20460 Official Business Penalty for Private Use \$300 751.0W

Kyle H. Sbinovic, Agent Shaldra, Inc.

4327 Reels Mill Rd. Frederick, MD 21704-7759

EPA Form 1320-3 (Rev. 3-84).





DP BARCODE: D250213

CASE: 062401

DATA PACKAGE RECORD

DATE: 10/08/98 SUBMISSION: S550000 BEAN SHEET Page 1 of 1

\* \* CASE/SUBMISSION INFORMATION \* \* \*

CASE TYPE: REGISTRATION ACTION: 362 AmD-TECH FORM CHG AMEND

CHEMICALS: 000595 Hydrogen peroxide 3.9800%

COMPANY:

PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B PM TEAM REVIEWER: TONY KISH 703-308-9443 ROOM: CS1 3W69

RECEIVED DATE: 09/04/98 DUE OUT DATE: 12/03/98

\* \* \* DATA PACKAGE INFORMATION \* \* \*

DP BARCODE: 250213 EXPEDITE: N DATE SENT: 10/08/98 DATE RET.:

CHEMICAL: 000595 Hydrogen peroxide

P TYPE: 001

CSF: Y LABEL: Y

ASSIGNED TO DATE OUT ADMIN DUE DATE: 11/22/98

DIV : AD 10/15/98 BRAN: EASSB 10 121 198 SECT: CTT

REVR : 1/1/1/2 CONTR: anna stanois

10-23-98 \* DATA REVIEW INSTRUCTIONS \* \* \*

Please review the attached chemistry data for acceptability.

\* \* \* DATA PACKAGE EVALUATION \* \* \*

No evaluation is written for this data package

\* \* \* ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION \* \*

DP BC BRANCH/SECTION DATE OUT DUE BACK INS CSF LABEL

NEGOT DATE:

PROJ DATE:

	Please read instructions on i	reverse before completing form.	<u>, , , , , , , , , , , , , , , , , , , </u>	Form Approved. Of	MB No. 2070-0050.	Approval expires 2-28-95
٠.		United States		* * * * * * * * * * * * * * * * * * *	gistration	OPP Identifier Number
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4	No No	No	No No		Glass	
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	1. Contact Point (Complete i	items directly below for identification	n of individual to be con	ntected, if necesses	ry, to pracess this a	pplication.)
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White - EPA File Copy (original)

Yellow - Applicant Copy

#### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Tony Kish
Registration Specialist
Antimicrobial Program Division (7510W)
US Environmental Protection Agency
Crystal Mall 2, Room 266A
1921 Jefferson Davis Hwy
Arlington, VA 22202

Re:Application for Pesticide Registration: H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 EPA File Symbol: 69268-E Corrected response to EPA letter of 07-22-98 OPP ID # 233313 09-02-1998

Dear Mr. Kish:

As suggested by Mr. Swindell, this letter is directed to you rather than to \$4s. Pam Hasty as you now have all the information on both of the Alphen, Inc. Products. In response to that £tter of 07-22-98 we are providing the following:

1. Transmittal letter.

Application for Pesticide Registration Form (OPP ID #233313).

 Copy of the CSF corrected to indicate the proper name of the product and of the as the verified pounds per gallon of this product. There are no other changes in the CSF.

Required Certification with Respect to Citation of Data using the new form.

- 5. Required data matrix using the new forms, since the active ingredient is from an unregistered source.
- Copy of letter from Patrick Stewart explaining the origins of the name of the products.
- 7. Three copies of Volume 1 Product Chemistry H<sub>2</sub>Orange, Concentrate 117 An Oxidizing Multipurpose, 1Step Cleaner, Degreaser. Sanitizer (Non-Food Contact Surfaces, Virucide, & Deodonizer for Hard Surfaces Revised Sections per EPA letter 07-22-98 only, Sections 61-3, and 53-17, and with a corrected Statement of NO Data Confidentiality.
  - Five copies of the label with the name adjusted to be identical to the name of the product on the CSF, and the signal word changed to Danger.

We now understand that you have all the required data for efficacy MRIDs have just had the reviews completed under EPA File Symbol 69268-R, and the information needed for these reviews are included in the submission for 69268-R.

I am also enclosing a copy of the Front-End response sheet and the pastmark on the envelope as again there was an extremely lengthy delay in sending the response out after the letter was written. It is this type repeated delay that forces Sponsor's to develop extremely high blood pressure and to feel that their particular project(s) are being ignored or set aside by the Agency.

Please let me know directly if you have additional questions regarding this product. Alphen is a very small company and is very anxious to have the registration of the products with at least conditional registrations so that they can introduce them at the Fall meeting of the National group that sponsors these types of products. Any assistance that you can give us would be greatly appreciated.

I would appreciate it if you would call me as soon as possible regarding the status of this product so that I can pick up the response letter.

Thank you for your assistance with this Application.

Sincerely yours,

Kyle H. Sibinovic, Ph.D.
Agent for Alphen, Inc.

•

193 ::

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division

DP Barcode D250213 Reg. No. or File Symbol 69268-2

Manufacturing-Use [ ] OR End-Use Product [ ]

TO: Marshall Swindell/Tony Kish
PM Team No. 33

\_\_\_\_\_

FROM: Anna Skapars, Chemist

Efficacy and Science Support Branch

THRU: Michelle Wingfield, Acting Chief

Efficacy and Science Support Branch

#### SUMMARY OF INFORMATION REVIEWED AND FINDINGS

Revised Confidential Statement of Formula dated 7-29-98 is in compliance with PR Notice 91-2, it agrees with the label and CSF is acceptable.

Provided product chemistry data for Suideline Series 61-3 discussion of formation of impurities and Series 63-17 Storage and stability data in MRID No. 446459-01 are acceptable. These data are in compliance with 40 CFR part 158.155 Through 158.190 and it satisfies product chimistry data for this product including the data for Sinis 61-3 and 63-17.

(logo)

H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-**POROUS SURFACES** 

ACTIVE INGREDIENT

Hydrogen peroxide

3.95%

OTHER INGREDIENTS

96.05%

TOTAL

100.00 %

KEEP OUT OF REACH OF CHILDREN

#### DANGER

#### PRECAUTIONARY STATEMENTS

SEE LEFT LABEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

with COMMENTS

in EPA Letter Dated:

ACCEPTED

EPA Reg. No. 069268-EPA Est. No. 069268-IL-001

SEP I 0 1998

ALPHEN, INC. MAPLE GROVE ROAD GEORGETOWN, IL 61846

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No. 69268-2

NET CONTENTS: 1 gallon

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

### PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMAN AND DOMESTIC ANIMALS

#### Statement of Practical Treatment

Danger. Undiluted product concentrate may cause severe eye damage. Do not get in eyes, on skin or clothing. Wear safety glasses or other eye protection and rubber gloves when handling concentrate. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.

#### In case of CONTACT with product concentrate

If in eyes: Flush immediately flush with cold water. Remove contact lenses. Continue flushing for 15 minutes, holding eyelids apart. Get prompt medical attention.

If on skin: Immediately wash with plenty of soap and water. Get medical attention.

If swallowed: Promptly drink large quantity of water. Avoid alcohol. Do not induce vomiting. Never give anything by mouth to an unconsious person.

#### STORAGE AND DISPOSAL

IN CASE OF SPILL: Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE**: Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL:** Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL**: Completely empty container. Do not reuse empty containers. Leave empty plastic bag in original box and discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.

ACCEPTED with COMMENTS in EPA Letter Dated:

SEP I 0 1998

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

69268-2

#### DIRECTIONS FOR USE

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

Alphen 117, when used as directed as a sanitizer, kills 99.99% or more of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruinosa, Streptococcus faecalis, and Escherichia coli. When used as directed as a virucide, Alphen 117 kills the following viruses in 5 minutes or less at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza AyJapan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces: Add 10 ounces of product concentrate per gallon of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution. Replace solution daily.

To use as a sanitizer and virucide in bathrooms: Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals, tollets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily.

HIV: To kill HIV in 5 minutes at room temperature (20-25° C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of Alphen 117 to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FILLIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned form surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officier.

ACCEPTED with COMMENTS in EPA Letter Dated:

SEP 1 0 1999

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

69268-2

#### **CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute with Alphen's Dispensing System Only)

LIGHT DUTY (1 Oz / gal) GREEN (bottle or label)
Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)
General wipe down cleaner
Mopping solution for Bathroom and Kitchen floors
General carpet spot remover

HEAVY DUTY (10 Oz / gal) RED (bottle or label)
Bathroom, shower room, tile & grout cleaner
Urine and garbage odor eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew

SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)
Renovation of tile & grout surfaces
Difficult urine & garbage odor destruction
Scuff marks and stubborn stains
Cleans heavy mold & mildew

1-Step Cleaning and Sanitizing: Using the appropriate cleaning solution for the type of surface to be treated, thoroubly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

#### Deodorizing

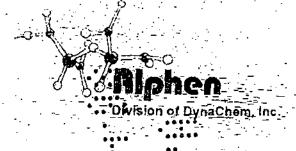
For general deodorizing, use 2 part Alphen 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts Alphen 117 to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

ACCEPTED with COMMENTS in EPA Letter Dated:

SEP 1 0 1998

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Req. No.

69268-2



# Memo

To: Kyle Sibinovic, Ph.D.

From: Patrick Stewart

Date: 07/28/98

Re: H<sub>z</sub>Orange<sub>2</sub> trade name

We "coined this product name in early 1997 and have been using it on our product labels, literature and trade advertising since that time. We have applied for trademark on both the name and the name with our logo. To my knowledge we have never had any comment concerning confusion as a result of the product name.

Thanks

🕶 Pago 1

Alphen, Inc., A Division of DynaChem -P.O. Box 19 - Maple Grove Road Georgetown, IL 61846 (217) 662-2130 FAX: (217) 662-2268

#### VOLUME 1

STUDY TITLE: PRODUCT CHEMISTRY - H2Orange2 Concentrate 117.-An Oxidizing Multipurpose, 1-Step Cleaner, Degreaser, Sanitizer (Non-Food Contact Surfaces, Virucide, & Deodorizer for Hard Surfaces

TEST ARTICLE: H2Orange2 Concentrate 117

Revised Sections per EPA letter 07-22-98 only, Sections 61-3, and 63-17

DATA REQUIREMENTS: 40 CFR 158 GUIDELINES

AUTHOR: KYLE H, SIBINOVIC, Ph.D., SHALDRA, INC., for Alphen, Inc.

LABORATORY PROJECT #: Alphen-98-PC-02

SUBMITTED TO: Alphen, Inc., a Div. Of DynaChem P.O. Box 19 - Maple Grove Road Georgetown, IL 61846

Attn: Patrick Stewart

SUBMITTED BY:

Shaldra, Inc.

4327 Reels Mill Road

Frederick, MD 21704-7759

Alphen, Inc., a Div. Of DynaChem P.O. Box 19 - Maple Grove Road

Georgetown, IL 61846

Sports of Submitter

Kyle P Sibinovic, Ph.D

Agent for Alphen, Inc.:

Denise Volimer

Regulatory Affairs/Quality Assurance

Bryan Bodart

Study Director

Access to FIFRA F		



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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		DATA MATRIX		<u> </u>	
Date 07-29-98			EPA Reg No. File Symbol 69268-E		Page(1) of 1
Applicant «Registrant » Name & Addres Alphen Inc., A.D P.O. Box, 19 - Map	iv Fof Dynachem le Grove Road, Georgetown, 11, 61846	J	Product H2 Orange2 Concentrate 117	, h	
Ingredient Hydrogen Peroxid	e				1
Guideline Reference Number	Guldeline Study Name	MRID Number	Submitter	Status	Note
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158.20 63-2 to 21	Product Chemistry	44532001	Alphen, Inc.	own	69268-R
158-135 <sub>1</sub> 84-1 to 6	Toxicology	44532004	OEL Criteria Document	PL	· /- /-
158.20 Efficacy	AOAC Sanitizer Test	44532002	Alphen, Inc.	awn .	69268-R
158.20 Efficacy	HIV Virucidal Test	44532003	Alphen, Inc.	gwn'	69268-R
158.20 Efficacy	Virucidal Effectiveness	44560101	Alphen, Inc.	own	69268-R
158.20 51+1 to 3	Product Chemistry	44582301	Alphen, Inc.	own	69268-E
158.20 62-1 to.3	Product Chemistry	44582301	Alphen .inc.	own	69268-E
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			Kyle H. Sibinovic, Ph.D., Agent		07-29-98

EPA Form 8570-35 (8-97) Electronic and Paper versions available. Submit only Paper version.

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Applicant's Registrant's Name & Address Alphen, Inc., A Oiv. of Dynachem P.O. Box 19 - Naple Grove Road, Geor		Product H2 'Orange	Concentrate 1,17		М Такай А Такай
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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C., 20460

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Do not send the completed form to this addless.	
Certification with Respect	
Applicant's Registrant's Name, Address, and Telephone Number Geo Alphen, Inc., Div. of Dynachem, P.O. Box19-Maple Grove Rd.	ergetown II EPA Registration Number/File Symbol 301-695-1200 69268-E
Active Ingredient(s) and/or-representative test compound(s)  Hydrogen Perox i de	- Oate - 07-29-98
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158 1 Step degreaser, sanitizer, virucide and deodorizer for hard	8) Product Name surfaces H2Orange2 Concentrate 117
NOTE: If your product is a 100% repackaging of another purchased EPA-registered this form. You must submit the Formulator's Exemption Statement (EPA Formulator's Exemption Statement (E	
I am responding to a Data-Call-in Notice, and have included with this form a be used for this purpose).	list of companies sent offers of compensation (the Data Matrix form show
SECTION I: METHOD OF DATA SUPP	PORT (Check one method only)
t am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	I am using the selective method of support (or cite-all option under the selective method), and have included with this form completed list of data requirements (the Data Matrix form must used).
SECTION II: GENERAL (	OFFER TO PAY
I hereby offer and agree to pay compensation, to other persons, with regard to	to the approval of this application, to the extent required by FIFRA.
SECTION (II: CERT	TIFICATION
I certify that this application for registration, this form for reregistration, or the application for registration, the form for reregistration, or the Data-Call-in response. In indicated in Section I, this application is supported by all data in the Agency's files that substantially similar product, or one or more of the ingredients in this product; and (2) requirements in effect on the date of approval of this application if the application sougues.	n addition; if the cite-all option or cite-all option under the selective method at (1) concern the properties or effects of this product or an identical or is a type of data that would be required to be submitted under the data
I certify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.	n or reregistration, that I am the original data submitter or that I have obtain
I certify that for each study cited in support of this registration or reregistration submitter, (b) I have obtained the permission of the original data submitter to use the compensation have expired for the study, (d) the study is in the public literature; or (e) offered (f) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c) amount and terms of compensation, if any, to be paid for the use of the study.	study in support of this application; (c) all-periods of eligibility for I have notified in writing the company that submitted the study and have
I certify that in all instances where an offer of compensation is required, cop accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be evidence to the Agency upon request, I understand that the Agency may initiate action FIFRA.	be submitted to the Agericy upon request. Should I fall to produce such in to deny, cancel or suspend the registration of my product in conformity v
l certify that the statements I have made on this form and all attachm knowingly false of misterding statement may be punishable by fine or impriso	neries to icage, due, accurate, and completeI acknowledge that any priment or both under applicable law
Signature Kylasselb no, PhQ	Oale Typed or Printed Name and Title 07-29-98 Kyle H. Sibinovic, PhD, Agent
	Andrew Communication and Communication of the Commu

PA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.

List of companies sent offers of compensation from the Data Submitters List

Active ingredient ... Hydrogen peroxide Chemical Id# 000595

1. ••• Company # 063394

Antimicrobial Exposure Assessment Task Force

2501 M St., NW

Washington, DC 20037

Data submitted:

Other Data - not specified

2. Company # not given

CSMA

1800 Wilson Blvd Arlington, VA 22209 Acute Toxicology

Data submitted:

Other Data

,SUBMISSION BAR CO.	de. # <u>\$54</u>	7637	_ REVIE	wer_PH	asif
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REVIEWER PHasy



## United States Environmental Protection Agency Washington, D.C. 20460

# Office of Prevention, Pesticides and Toxic Substances Office of Pesticide Programs Antimicrobial Division

FAX Number (703) 308-6467

## FACSIMILE REQUEST/COVER SHEET (Please type or print clearly in black ink only)

Name: KylE SibiNovic
Office:
FAX Phone No. 301-695-1409
Office Phone No.
FROM: Jony Kish
Division/Branch:
Office Phone No.
Office Room No.
Mail Code: Date: 9/30/98 Time:
Number of pages (with this cover sheet):
Special Message: Registration retrices for EPA Reg = 69268-R  And 69268-E. Please Note that Alphan is Responsible  FOR Offering compensation not say to companies
on the data submitters list but 12/50 to companies
Responsible FOR studies (eg fisht wildlife) listed in the RED FOR HOD. Your client must do this because
HO- 13 AN UNREGISTERED SOURCE OF ACTIVE INGREDIENT
if knows to hold relevant data on 120.



#### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs Registration Division (H7505C)

69268-2

Date of issuance:

SEP 1 0 1998

"M" St, 5.W.

Washington, D.C. 20460

Term of Issuance:

EPA Reg. Number:

CONDITIONAL.

Name of Pesticide Product:

H<sub>2</sub>ORANGE, **CONCENTRATE 117** 

NOTICE OF PESTICIDE:

x Registration

Reregistration

(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code): Alphen, Inc.

Division of Dynachem

P.O. Box 19, Maple Grove Road

Georgetown, IL 61846

Note: Changes in labeling differing in substance from their accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the laber in cummerce. In any correspondence on this product always refer to the above EPA registration number

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time respend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if if has been covered by

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

- 1. Submit and/or cite all data required for registration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.
  - 2. Add the phrase EPA Registration Number "EPA Reg. No. "69268-2".

Signature of Approving Official:

Marshall Swindell

Product Manager 33

Swindel Regulatory Management Branch 1 Antimicrobial Division (7510W)

Date:

SEP 1 0 1998

EPA Form 8570-6

page 2 EPA Reg. No. 69268-2

3. This conditional registration will expire automatically in exactly 12 months (365 calendar days) from the date stamped on this Notice of Pesticide Registration unless you meet the condition stated below. If you fail to satisfy this condition imposed in the registration, EPA may issue a Notice To Cancel under section 6(e) of FIFRA.

You must submit three copies of: (a) raw data from all the efficacy studies that were submitted for review, and (b) characterization data (identity, strength, purity, and composition of test substances for lot numbers 97199, 97220, 97227, 168, 181, 97168, 97181, 10003, 10004, 10053, and 10054). If EPA verifies and accepts (within the 12 month time restriction) that the efficacy data were developed at the proper concentrations, then a conditional registration can be issued without the 12 month time limitation.

- 4. Increase the type size of the Signal Word "DANGER" to conform to the latest edition of the EPA Label Review Manual.
- 5. Move the "Statement of Practical Treatment" boldfaced heading so that it is flush left, and just before "In case of CONTACT with product concentrate".
  - 6. Submit two copies of the revised final printed label for the record.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Tony Kish at (703) 308-9443.

Sincerely,

Marshall Swindell

Product Manager 33

Regulatory Management Branch 1 Antimicrobial Division (7510W)

Enclosure

lor

(logo)

## H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD, NON-**POROUS SURFACES** 

ACTIVE INGREDIENT

Hydrogen peroxide

3.95%

OTHER INGREDIENTS

96.05%

TOTAL

100.00 %

#### KEEP OUT OF REACH OF CHILDREN

#### DANGER

#### PRECAUTIONARY STATEMENTS

#### SEE LEFT LABEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

ACCEPTED with COMMENTS in EPA Letter Dated:

EPA Reg. No. 069268-EPA Est. No.

069268-IL-001

SEP 1 0 1998

ALPHEN, INC. MAPLE GROVE ROAD GEORGETOWN, IL 61846

Under the Federal Insecticide, Pungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

69268-2

NET CONTENTS: 1 gallon

**NET WEIGHT:** 

This product is not to be used as a terminal sterilant/disintectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

#### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMAN AND DOMESTIC ANIMALS

#### Statement of Practical Treatment

**Danger.** Undiluted product concentrate may cause severe eye damage. Do not get in eyes, on skin or clothing. Wear safety glasses or other eye protection and rubber gloves when handling concentrate. Avoid contamination of food. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required. Product, after dilution according to directions, is non-irritating.

#### In case of CONTACT with product concentrate

If in eyes: Flush immediately flush with cold water. Remove contact lenses. Continue flushing for 15 minutes, holding eyelids apart. Get prompt medical attention.

If on skin: Immediately wash with plenty of soap and water. Get medical attention.

If swallowed: Promptly drink large quantity of water. Avoid alcohol. Do not induce vomiting. Never give anything by mouth to an unconsious person.

#### STORAGE AND DISPOSAL

IN CASE OF SPILL: Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

STORAGE: Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL**: Do not contaminate water, food or feed by disposal. Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL**: Completely empty container. Do not reuse empty containers. Leave empty plastic bag in original box and discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.

ACCEPTED with COMMENTS in EPA Letter Dated:

SEP 1 0 1998

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

69268-2

#### **DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

Alphen 117, when used as directed as a sanitizer, kills 99.99% or more of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruinosa, Streptococcus faecalis, and Escherichia coli. When used as directed as a virucide, Alphen 117 kills the following viruses in 5 minutes or less at room temperature (20+/-1°C): Herpes simplex virus Type 2, Influenza A<sub>2</sub>/Japan, and HIV-1 (Human Immunodeficiency Virus). To insure that all bacterial and viral agents are killed as stated, use 10 oz. of product concentrate per gallon of water.

To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces: Add 10 ounces of product concentrate per gation of water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily solled surfaces should be pre-cleaned with the same solution. Replace solution daily.

To use as a sanitizer and virucide in bathrooms: Add 10 oz. of product concentrate per gallon of water for sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up. Replace solution daily.

HIV: To kill HIV in 5 minutes at room temperature (20-25° C) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of Alphen 117 to 127 parts of water). For use in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1 Associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:

Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned form surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution.

Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label.

Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officier.

ACCEPTED with COMMENTS in EPA Letter Dated:

SEP 1 0 1998

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

69268-2

#### CLEANING SOLUTION DILUTIONS & APPLICATIONS

(Dilute with Alphen's Dispensing System Only)

LIGHT DUTY (1 Oz / gai) GREEN (bottle or label)
Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gal) BLUE (bottle or label)
General wipe down cleaner
Mopping solution for Bathroom and Kitchen floors
General carpet spot remover

HEAVY DUTY (10 Oz / gal) RED (bottle or label)
Bathroom, shower room, tile & grout cleaner
Urine and garbage odor eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew

SUPER DUTY (24-48 Oz / gal) PURPLE (bottle or label)
Renovation of tile & grout surfaces
Difficult urine & garbage odor destruction
Scuff marks and stubborn stains
Cleans heavy mold & mildew

1-Step Cleaning and Sanitizing: Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution. Replace solution daily.

Deodorizing

For general deodorizing, use 2 part Alphen 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts Alphen 117 to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

ACCEPTED with COMMENTS in EPA Letter Dated:

SEP 1 0 1998

Under the Federal Insecticide, Pungicide, and Rodenticide Act as amended, for the pesticide, registered under EPA Reg. No.

69268-2

### EFFICACY AND SCIENCE SUPPORT BRANCH

#### **EFFICACY REVIEW - I**

#### ANTEMICROBIAL DIVISION

IN <u>06/16/98</u>	OUT08/21/98
	69268-E(4% A.I. H202 ba
Sanwoas	Date 08/21/98
Reviewed by <u>Srinivas Gowda</u>	Date
EPA Reg. No. or File Symbol_	69268-R(8% A.I. H20)
LAN Code	
EPA Petition or EUP No	None
Date Division Received	05-20-98
Type Product	Non-Food Contact Surface Sanitizer
MRID No (s) 4453	20-02, 445320-03, and 445601-01
Product Manager	PM 31 (MSwindell)
PM Team Reviewer	Tony Kish
Product Name H2ORANGE,	SUPER CONCENTRATE 112
Company Name	ALPHEN, INC.
Submission Purpose	New Application
Type Formulation	Liquid
Active Ingredient (a):	·
Hydrogen peroxide	7.95

#### EFFICACY AND SCIENCE SUPPORT BRANCH

#### EFFICACY REVIEW - II

### ANTIMICROBIAL DIVISION

EPA Reg. No.	or File Symbol	69268-R	
LAN Code			
EPA Petition	or EUP No	None	
Date Division	n Received	05-20-98	
Type Product		Non-Food Contact Surface Sam	nitizer
MRID No (s)_	445320	-02, 445320-03, and 445601-0	1
Product Mana	ger	PM 31 (MSwindell)	· 
PM Team Revi	ewer	Tony Kish	
Product Name	H2ORANGE2 ST	JPER CONCENTRATE 112	
Company Name		ALPHEN, INC.	

#### 202.0 Recommendations

#### 202.1 Efficacy Supported by the Data:

The submitted data by the Modified EPA's Sanitizer Test Method appear adequate to support effectiveness of the product as a non-food contact surface sanitizer against Salmonella choleraesuis ATCC 10708, Staphylococcus aureus ATCC 6538, Pseudomonas aeruginosa ATCC 15442, Klebsiella pneumoniae ATCC 4352, Escherichia coli ATCC 25922, and Streptococcus faecalis 19433 and when used at a concentration of 1450 ppm hydrogen peroxide on precleaned, hard, non-porous surfaces for a contact time of 5 minutes at room temperature. However, the final acceptance is pending upon the submission of additional information/data as indicated under 202.2.

Also, the submitted data by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against HIV-1(AIDS virus) when tested at 2.710 g. concentrate + 997.3 g of 415.6 ppm synthetic hard water and 2.778 g. concentrate + 997.2 g of 415.6 ppm synthetic hard water dilutions on hard, non-porous surfaces in the presence of 5% blood serum for a contact time of 5 minutes at 21°C. However, the final acceptance is pending upon the submission of additional information/data as indicated under 202.2.

Also, the submitted data by the EPA's Virucidal Test Method appear adequate to support effectiveness of the product as a virucide against Herpes simplex virus Type II ATCC VR-734 and Influenza A<sub>2</sub> /Japan/305/57,ATCC VR-100 when tested at a concentration of 500 ppm hydrogen peroxide (13.889 ml. product + 986.11½ ml. sterile deionized water) on precleaned, hard, non-porous surfaces for a contact time of 5 minutes at 20°C. However, the final acceptance is pending upon the submission of additional information/data as indicated under 202.2.

#### 202,2 Additional Data/Information Required to Support Efficacy:

- a. Submit raw data of all three studies.
- b. Submit characterization data (identity, strength, purity, and composition of test substances, lot numbers 97199, 97220, 97227, 168, 181, 97168, 97181, 10003, 10004, 10053, and 10054) to verify if the efficacy data were developed at the proper concentrations.

#### 203.0 Labeling:

The proposed product name "H<sub>2</sub>ORANGE<sub>2</sub> SUPER CONCENTRATE 112" is not acceptable. Propose another name.

On the Front Panel:

- a. delete "...1-STEP CLEANER..." because the sanitizing data were not developed in the presence of 5% blood serum to support one-step sanitizing claim.
- b. "Virucide" claim must be keyed by a symbol to the paragraph listing the tested viruses. Therefore, change "...VIRUCIDE..." to "...VIRUCIDE\*...".
- c. Change "...HARD SURFACES..." to read "...HARD NON-POROUS SURFACES..."

On the Right Panel change "1-Step Cleaning and Sanitizing:" to read "For Cleaning and Sanitizing:", and change "...thoroughly clean the surface, allow to air dry" to read "...thoroughly clean the surface, then apply same solution to the surface to sanitize, allow to remain wet for 5 minutes and air dry."

On the Back Panel change "...kills 99.99..." to read "...kills 99.9%..."

On the Back Panel change "... Herpes 2..." to read "... Herpes simples Type 2..."

#### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Tony Kish
Registration Specialist
Antimicrobial Program Division (7510W)
US Environmental Protection Agency
Crystal Mall 2, Room 266A
1921 Jefferson Davis Hwy
Arlington, VA 22202

09-09-1998

Re:Application for Pesticide Registration:
H<sub>2</sub>Orange<sub>2</sub> Concentrate 117
EPA File Symbol: 69268-E
Response to EPA verbal request of 09-08-98 for labels
OPP ID # 233334

Dear Mr. Kish:

As requested in our discussion regarding the Master Label for the above referenced product, we are providing the following:

1. Transmittal letter.

2. Application for Pesticide Registration Form (OPP ID #233334).

3. Five (5) copies of the Master Label corrected in accordance with your instructions.

Please let me know directly, if you have additional questions or changes regarding this product. The Sponsor greatly appreciates your assistance with this project.

I would appreciate it if you would call me as soon as possible regarding the status of this product so that I can pick up the registration letter as quickly as possible.

Thank you for your assistance with this Application.

Şincerely you<u>r</u>s,

Kyle H. Sibinovic, Ph.D. Agent for Alphen, Inc.

Please read instructions on reverse before completing form.	Form App	roved - OMB No.	2070-0060	. Approval expires 2-28-95
SEPA Environmental Protection Age	ncy	Registra		OPP Identifier Number
Washington, DC 20460		Other		
Application for t	Pesticide - Sect	ión I	4, 1, 1	
1. Company/Product Number 59258-E	2. EPA Product Mana	ider A. A. Car	3. Pro	posed Classification
4. Company/Product (Name) H20range2 Concentrate 117	PMI TOUR SOUTH	mare of the state	للله الأيَّ	None
5. Name and Address of Applicant <i>linclude ZIP Codel</i> - Alpnen, Inc., a Div. of Dynachem Maple Grove Road Georgetown, IL 61846	8. Expedited Revi	iew In accorda s-similar or idem products	ince with f ical in con	FIFRA Section 3(c)(3)
Check if this is a new address	Product Name	والمراجع والمراجع والمراجع والمراجع	<sub></sub>	
Sec				P. J. A. BOTTE B. T. WAS A WAY.
Amendment - Explain below  Resubmission in response to Agency letter dated	Final printed	I labels in respons or deted opplication	erto Si To 1	A TELEPHONE TO THE STATE OF THE
Notification - Explain balow.	Other Expl	ain below.		
Submission of Master Labels corrected in accordance with	And the contract			
Sec	tión III			Salar Carlo Bridge ( W.
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1. Contact Point (Camplete items directly below for identification of indiv	dust to be contacted,	il nacessary, to pi	ocass this	application.)
Name  Kyle H. Sibinovic, Ph.D.  Agent	a grander March Ra	A SECTION OF THE SECT	S. P. 105	No. (Include Area Code)
Certification  I certify that the statements I have made on this form and all attach I acknowledge that any knowingly false or misleading statement me both under applicable law				6. Date Application Received  (Stamped)
2. Signature  4. Additional Agent	And American			
4. Typed Name 5. Data	00			212

#### PAPERWORK-REDUCTION ACT NOTICE and INSTRUCTIONS Sec. 13.

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to average 0.85 hour pe response, including time for reviewing instructions, searching existing data sources, galhering and meintaining the data needed, and completing and reviewing the collection of information. Send comments regerding the builden estimate of any other espect of this collection of information, including suggestions for reducing this burden, to Chief, information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW. Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget. Washington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for now registration; and use reregistration, amendment, resultinission, to applications for notifications, final printed labeling, recogistration, etc. In older to process an application for a how registration submitted on this form, the THERE following material must accompany the application:

ر با دو مخاطعه في المراجع مستحيد

- 1. Cortification with Respect to Citation of Data (EPA Form 8570-29). Ill not exempted by 40 CFR 152.81 (b) (4));
- "Confidential Statement of Formula (EPA Form 8570:41)
- Formulator's Examption Statement (EPA Form 8570-27);
- Five copies of draft labeling:
- 5. Three copies of any data submitted:
- Authorization letter where applicable;
- Metricas where applicable.

Submission of Labeling - Lebeling should first be submitted in the form of distributed by with all applications for new togistration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission of a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8:5 x 11 inch file Mockup labels significantly smaller, than 8.5 x 11 inches should be mounted on 8:5 x 11 Inch paper for submission.....

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86.5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration ection. listed in Block A. for which you are submitting this application. For applications submitted in connection with New Registration actions. Section I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

SECTION 1 - This section must be completed, as applicable, for all registration actions.

- Company/Product Number Insert your Company Number, if one has been assigned by EPA. Title number may have been assigned to you as a basic registrent, a distributor, or as an establishment. If your product le registered, Insert the Product Number.
- EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- Proposed Classification Specify the proposed classification of this product
- Product Name Enter the complete product name of this pecticide as it will appear on the label. The name must be specific to this product only
- Duplication of names is not permitted among products of the same company: Do not include any brend name or company line designations.
- Name and Address of Applicant. The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are ecting in behalf of another party; you must submit authorization from that party to act for them in registration metters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
- Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

SECTION II - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration. 答

1. Subject of submission - Check the applicable block and provide the Agency latter date if appropriate. Provide a brief explanation of the purposate for the submission, such as "the addition of a site, pact of crop (specify); "amend the Confidential Statement of Formula by... ( reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed:

SECTION III (Packaging and Contiliner Information). This Section must be completed for all applications submitted in connection with new registration or applicable amandments.

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the Indicated packaging types. Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indicate type of container in which product will be marketed
- Location of Net Contents: Indicate the location of the net contents information for your product.
- Size(e) of Retail Container Specify the net contents of ell retail containers for your product.
- Location of Use Directions Indicate the location of the use directions for your product.
- 8. Monner in which label is affixed to product indicated the method product label is attoched to retail container.

SECTION IV (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
- EPA Use Only.

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division

DP Barcode Reg. No. or File Symbol 69268-E

Manufacturing-Use [ ] OR End

OR End-Use Product [1

TO:

Marshall Swindell Tony Kish PM Team No. 33

FROM:

Anna Skapars, Chemist

Efficacy and Science Support Branch

THRU:

Michelle Wingfield, Acting Chief

Efficacy and Science Support Branch

#### SUMMARY OF INFORMATION REVIEWED AND FINDINGS

Provided chemical identity of and has been cleared and per codes have been assigned and they may be used in this formulation.

Confidential Statement of Formula dated 4-6-98 complies with PR Notice 91-2 and all ingredients in CSF are cleared and CSF is a cceptable.

For strage and stability data testing for the activity ingredient should be done at the beginning of strage few times device storage and at the send of strage and stability as a reported.

anna Skapas

\*Inert ingredient information may be entitled to confidential treatment\*

# CHEMICAL NAME/PESTICIDE CHEMICAL CODE (PCC) REQUEST FORM'

Please Expidite FORA

	apais	REQUEST DATE: 9/2/98
TEL.:( )308-8326 ORG.:		ROOM: MAIL CODE:
CSF ATTACHED:	316.)	
YES If CSF is attached complete Itel		
NO If CSF is not attached complete	e Items A through	<b>C.</b>
A DIFORMATION DEGLIDED.		•
A. INFORMATION REQUIRED:  Classic Applicable Category		
Provide PCC and Tolerance Exemption		Ise Inert Ingredient(s)
Provide PCC for Non-Food Use Inert In	gredient (s)	•
<ul><li>Provide PCC for Active Ingredient(s)</li><li>Provide PCC for Dye</li></ul>		
Determine if Fragrance is Acceptable for	Use in Formulat	ion
Other (Describe):		
D. INCOUNTEMEDICABLESSON.		·
B. INGREDIENT INFORMATION:		
Ingredient No. 1:	Lagredient	No. 2:
-		
Chem. Name:	Chem. Nan	16:
Trade Name:	Trade Nam	e:
CAS Reg. No.:	CAS Reg. ?	
		Nt. 4.
Ingredient No. 3:	Ingredient	No. 4:
Chem. Name:	Chem. Nan	1e:
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Trade Name: CAS Reg. No.:	Trade Nam CAS Reg. !	
		•
C. PESTICIDE PRODUCT INFORMATION:		
EPA Reg. No./File Symbol: 69268-E Pr	oductName: Ha	Orange Suger Concentr
Registrant: Alakin		Food-Use Pesticide: YES MO
	oly):	<u> </u>
Percent in Formulation (For Fragrance/Dyes o		
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FORMA Ingred	Ingrédient No	. 2.
Ingred	PCC:	
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Alphen, Inc... A Division of DynaChem : P.O. Box 19 - Maple Grove Road Georgetown, IL 61846 (217) 562-2130 FAX: (217) 662-2268

#### **VOLUME 1**

STUDY TITLE: PRODUCT CHEMISTRY - H2Orange2 Concentrate 117 -An Oxidizing Multipurpose, 1-Step Cleaner, Degreaser, Sanitizer (Non-Food Contact Surfaces, Virucide, & Deodorizer for Hard Surfaces

TEST ARTICLE: H2Orange2 Concentrate 117

Revised Sections per EPA letter 07-22-98 only, Sections 61-3, and 63-17

DATA REQUIREMENTS: 40 CFR 158 GUIDELINES

AUTHOR: KYLE H, SiBINOVIC, Ph.D., SHALDRA, INC., for Alphen, Inc.

LABORATORY PROJECT #: Alphen-98-PC-02

SUBMITTED TO: Alphen, Inc., a Div. Of DynaChem P.O. Box 19 - Maple Grove Road Georgetown, IL 61846

Attn: Patrick Stewart

SUBMITTED BY:

Shaldra, Inc.

4327 Reels Mill Road

Frederick, MD 21704-7759

and .

Alphen, Inc., a Div. Of DynaChem

P.O. Box 19 - Maple Grove Road

Georgetown, IL 61846

Sponsor/Submitter

Kyle PSibinovic, Ph.D.

Agent for Alphen, Inc.

Denisc Vollmer

degulatory Affairs/Quali

L	GRA NO. 69268-2
Page	is not included in this copy.
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I	Identity of product inert ingredients.
1	Identity of product impurities.
I	Description of the product manufacturing process.
I	Description of quality control procedures.
1	Identity of the source of product ingredients.
£	Sales or other commercial/financial information.
A	A draft product label.
т	The product confidential statement of formula.
	prormation about a pending registration action.
F	FIFRA registration data.
т	The document is a duplicate of page(s)
	The document is not responsive to the request.
I	Internal deliberative information.
A	attorney-Client work product.
	Claimed Confidential by submitter upon submission to the agency.

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STATUS

RESPONSE CODE

RESPONSE, DATE

Please read instructions on reverse before completing form:	Form Approved	OMB No. 2070-0060	Approval expires 2-28-95
United States		Registration	OPP Identifier Number
Environmental Protection A	gency 🔑 😘	Amendment	992949
Washington, DC 20460		Other:	233313
Application fo	Pesticide - Section	Constant sales	Sign of the state
	2: EPA Product: Manager		posed Closeification
I. Company/Product Number 69268	marshall ?	الماقتين والمنازية	THE PARTY OF THE P
4. Company/Product (Name) H 2 Oranga 2	PMI 3.3		None Restricted:
Concentrate 117	A Shirt Distance		
5. Name and Address of Applicant (Include ZIP Code)	6. Expedited Review.		
Alphan The Alexander	(b)(i) my product is sim	ilacior identical in coi	nposition and labeling
Po Box 19 - maple brown	QI EPA Reg No. 69	268-13	The transfer of the
- Genderfour Tillian		では、	Se Oriental Signature
Chack is that is a new address.	Product Name 100	cange & Du	perclane 112
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Amendment Explain below	Final printed labe	s in response to	The state of the s
Resubmission in response to Agency letter dated	Agency letter dat		1 14 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Notification - Explain below.	Other - Explain be	NOW.	स्ट्रियाक्षेत्रः इति विद्यापात्
Explanation: Use additional pagets) if necessary, (For section Land	Section II.) Respon	29 John	10 Hery 07-22-18
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1. Contact Point   Complete items directly below for identification of in	dividual to be contacted, if nec	essary, to process this	application.)
Name Kula H SIBINOVICAD Tile	FrapA	Telephon	Ne (Include Area Code)
Certification	schments thereto are true, occ	urate and correlates	6. Dete Application The Control of t
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#### PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is estimated to everage 9.85 hour i response, including time for reviewing instructions, searching easiling date courses, gethoding and maintaining the date needed, and completing and reviewing the collection of information. Send comments regarding the builden extends or any other expect of this collection of information, including suggestions for reducing this burden, to Chief. Information Policy Branch, (2738), U.S. Environificing this burden, to Chief. Information Policy Branch, (2738), U.S. Environificing Protection, Agency, 401 M. Street: SW. Weshington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Weshington, DC 20503.

INSTRUCTIONS: This form is to be used for all applications for new registration, and use, rargeistration, amendment, resubmission, to application for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application

- 1. Certification with Respect to Citation of Dela (EPA Form 8570-29). [If not exampled by 40 CFR 152.8] (b) (4)];
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- 3. Formulator's Examption Statement (ERA Form 8570-27);
- 4. Five copies of draft labeling;
- Three copies of any date submitted;
- Authorization letter where applicable;
- 7. Metrices where applicable.

Submission of Labeling - Labeling should first be submitted in the form of draft labels with all epolications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission of a mackup of the proposed label. If prepared for mackup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inchas should be mounted on 8.5 x 11 inch paper for submission.

Submission of Data - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A. for which you are submitting this application. For applications submitted in connection with New Registration ections, Sections I. Ill: and IV must be completed by the applicant For applications submitted in connection with amended relegistration ections, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A - Check the appropriate action for which you are submitting this form.

SECTION 1 - This soction must be completed, as applicable, for all registration actions.

- Company/Product Number. Insert your Company Number, if the has been assigned by EPA. This number may have been assigned to you as basic registrent, a distributor, or as an establishment. If your product is registered, insert the Product Number. 💝 🚿
- EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.
- 3. Proposed Classification Specify the proposed classification of this product.
- Product Name Enter the complete product name of this posticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations:
- Name and Address of Applicant. The name of the firm of person and address shown in your application is the person or firm to whom the registration will be issued. If you are eating in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an egent must accompany this application.
- Expedited Review FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or emending its to extend the residence of applications for registration. that are similar or identical to other posticide products that are currently registored with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical toyour product. The product must be similar or identical in both formulation and labeled uses.

SECTION II . This section must be completed for all applications submitted to amend the registration only of a currently registered product. (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other scuon that partains to a specific EPA registered product. This section is not to be used for a new application for registration.

Subject of submission - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purposels submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packoping and Container Information) - This Section must be completed for all applications submitted in connection with new •.⊎. 學學的 registration or applicable amondments. Charles of the Contract

- Type of Packegling. Check the engrepriets block if your product will be packeded in the indicated packeging types Indicate the size of the individual packets and number per retail container.
- 2. Type of Retail Container Indigate Type of container in which product will be marketed.
- 3. Location of Nat Contents Indicate the location of the net contents information for your product.
- 4. Size(a) of Retail Container Specify the net contents of all retail containers for your product.

  5. Location of Use Directions indicate the location of the use directions for your product. 6. Manner in which label is affixed to product - indicated the method product label is attached to retail container.

- SECTION IV (Confect Point) This Section must be completed for all applications for Registration actions, i.e., new products registration resubmission, "mo too," pregistration, etc.
- 1-5. Self-explanatory.
- EPA Use Only.

(logo)

H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD SURFACES

ACTIVE INGREDIENTS
Hydrogen peroxide

3.95%

OTHER INGREDIENTS

96.05%

TOTAL

100.00 %

KEEP OUT OF REACH OF CHILDREN

#### CAUTION

#### PRECAUTIONARY STATEMENTS

SEE LEFT LABEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 069268-EPA Est. No. 069268-IL-001

> ALPHEN, INC. MAPLE GROVE ROAD GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

**NET WEIGHT:** 

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

#### PRECAUTIONARY STATEMENTS

# CAUTION HAZARDS TO HUMAN AND DOMESTIC ANIMALS KEEP OUT OF REACH OF CHILDREN

#### STATEMENT OF PRACTICAL TREATMENT

in case of CONTACT, Concentrate causes moderate eye irritation, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician if irritation persists. Remove and wash contaminated clothing before reuse. Product, after dilution according to directions, is non-irritating. If SWALLOWED, Drink promptly large quantity water. Call a physician immediately, if large amount ingested.

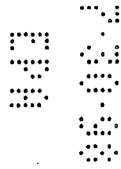
**Caution**. Concentrate may cause eye irritation. Do not get in eyes. Wear safety glasses or other eye protection when handling. Avoid contamination of food. Wash thoroughly after handling. (After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required.)

IN CASE OF SPILL: Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE**: Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by disposal. Wastes fresulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Completely empty container. Do not reuse empty containers. Leave plastic bag in original box discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.



#### DIRECTIONS FOR USE

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

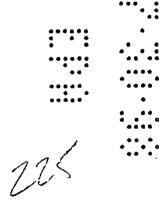
Alphen 117, when used as directed as a sanitizer, kills 99.99% or more of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruinosa, Streptococcus faecalis, and Escherichia coli. When used as directed as a virucide, Alphen 117 kills the following viruses in 5 minutes at room temperature (20+/-1°C): Herpes 2 and Influenza A/Japan. HIV-1 (Human Immunodeficiency Virus), is killed at a concentration of 1 oz per gallon (1 part of product plus 127 parts of water) in 5 minutes at room temperature. However, to insure that all bacterial and viral agents are killed as stated, the higher concentration of active (10 oz/gallon) should be used.

To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces: Add 10 ounces of this product per gallon of deionized water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution, then, treated for sanitizer or virucidal effect.

To use as a sanitizer and virucide in bathrooms: Use above procedure on sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up.

HIV-1: Kills HIV-1 (Humen immunodeficiency viurs) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of Alphen 117 to 127 parts of water), in 5 minutes at room temperature (20 - 25°C) in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1) (Associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned form surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution. Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label. Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officier.



#### **CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute manually with satellite measuring bottle)

LIGHT DUTY (1 Oz / gallon ) GREEN
Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gallon ) BLUE General wipe down cleaner Mopping solution for Bathroom and Kitchen floors General carpet spot remover HEAVY DUTY (10 Oz / gallon ) RED Bathroom, shower room, tile & grout cleaner Urine and garbage odor eliminator Pre-spray for carpet extraction General degreaser Heavy soil wipe down cleaner Heavy carpet spot remover Cleans Mold & mildew

SUPER DUTY (24-48 Oz / gallon) PURPLE Renovation of tile & grout surfaces Difficult urine & garbage odor destruction Scuff marks and stubborn stains Cleans heavy mold & mildew

**1-Step Cleaning and Sanitizing:** Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution.

#### Deodorizing

For general deodorizing, use 2 part Alphen 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts Alphen 117 to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.



### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

WASHINGTON, D.C. 20460

Paparwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for registration and 0.25 hours per response for registration and on special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460.

Do not send the completed form to this address.					
Certification with Respect to Citation of	Data				
Applicant's/Registrant's Name, Address, and Telephone Number Georgetown It. 61846 Alphen, Inc., Div. of Dynachem, P.O. Box19-Maple Grove Rd. 301-695-1200	EPA Registration Number/File Symbol 69268-E				
Active Ingredient(s) and/or representative test-compound(s)  Hydrogen Peroxide	Oate 07-29-98				
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)  1 Step degreaser, samitizer, virucide and deodorizer for hard surfaces	Product Name HgOrange2 Concentrate 117				
NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).	rall the same uses on your label, you do not need to				
I am responding to a Data-Call-In Notice, and have included with this form a list of companies se be used for this purpose).	nt afters of compensation (the Data Matrix form should				
SECTION I: METHOD OF DATA SUPPORT (Check one m	einad anly)				
a list of companies sent offers of compensation (the Data Matrix form under the	g the selective method of support (or cite-all option selective method), and have included with this form a d list of data requirements (the Data Matrix form must be				
SECTION II: GENERAL OFFER TO PAY					
[Required if using the cite-all method or when using the cite-all option under the selective method to satisf	y one or more data requirements)				
X I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this	application, to the extent required by FIFRA.				
SECTION III: CERTIFICATION					
i certify that this application for registration, this form for reregistration, or this Data-Call-in response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-in response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.					
I certify that for each exclusive use study cited in support of this registration or reregistration, the written permission of the original data submitter to cite that study.	at I am the original data submitter or that I have obtained				
I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter. (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study. (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.					
I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIERA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIERA.					
I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowledgy false or misleading statement may be punishable by fine or imprisonment or both under applicable faw.					
Signature Kyleddham The Date 07-29-98	Typed or Printed Name and Tite.  Kyle H. Sibinovic, PhD, Agent				
PA Form 8570-34 (9-97) Electronic and Paper versions available. Submit only Paper version.					



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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		DATA MATRIX	·		11
Date : 07-29-98	1		EPA Reg No./File Symbol 69268-E		Pegal Liof 1
Applicant s/Registrant's Name & Addres Alphen Inc., A.t P.O. Box 19- Mar	olv. of Dynachem ole Grove Road, Georgetown, IL 61846		Product H2 Orange2 Concentrate 117		
Ingredient Hydrogen Peroxic	de				Para Property
Guideline Roference Number	Guideline Study Name	MRID Number	Submitter	Status	Nate
158.20 61-1 to 3	Product Chemistry	44532001	Alphen, inc	own	HyuOnangez Super Concentrate 112
158-20 62-1 to 3	Product Chemistry	44532001	Alphen, inc	own .	69,268-R
158.20_63-2_to_21	Product Chemistry	44532001	Alphen, los	own	69268-R
158-135 81-1 to 6	Toxicology	44532004	OEL Criteria Document	PL	y '   _e-
158.20 Efficacy	AOAC Sanitizer Test	44532002	Alphen, Inc.	own.	69268-R
158.20 Efficacy	HIV Virucidal Test	44532003	Alphen, Inc.	OWN	69268-R
158.20 Efficacy	Virucidal Effectiveness	44560101	Alphen, Inc.	own	59268-R
158.20 61-1 to 3	Product Chemistry	44582301	Alphen, Inc.	own	11 .1 69268-E
158.20 62-1 to 3 ·	Product Chemistry	44582301	Alphen .inc.	owń	69268-E
158.20 63-2 to 21	Product Chemistry	44582301	Alphen, Inc.	awri	69268-E
? }	$\mathcal{L}_{\mathcal{L}}}}}}}}}}$				(1) (1) (1)
<u> </u>					1.5 Mg/M3 3.1 Mg/M3
					6
Signature Kalkelle	Contrand Proces yearlong available Schmidt and Flores year	,	Name and Tille : Kyle H: Sibinovic, Ph.D., Agent	· · · · · · · · · · · · · · · · · · ·	Юма <sup>1</sup> 107-29-98

EPA Form 8570-35 (8-97) Electronic and Paper versions available. Submit only Paper version.

Agoncy internal Use Copy"





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per registration activities and 0.25 hours per registration activiti

DATA MATRIX			
ate 07-29-98	EPA Reg No /Fite Symbol 69268-E		Page 1 of 1
pplicant's/Registrant's Name & Address Alphen, Inc., A Div. of Dynachem P.O., 80x 19 - Maple Grove Road, Georgetown, IL 61846	Product H2 Orange2 Concentrate	117	
gredient Liydfogen Peroxide			
ujdeline Reference Number Guideline Study Name MRID Numb	er Submitter	Status	Note
	Alphen, inc.	1 Qwn 1 (-11)	Hy Orangey- Supe Concentrate 11
	Alphen, Inc.	own I	69268-R
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	Alphen, Inc.	own .	.69268-R
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EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.	Kyle H. Sibinovic, Ph.D., Agen	. । । । । । । । । । । । । । । । । । । ।	107-29-98

#### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Pam Hasty
Registration Specialist
Antimicrobial Program Division (7510W)
US Environmental Protection Agency
Crystal Mall 2, Room 266A
1921 Jefferson Davis Hwy
Arlington, VA 22202

Re:Application for Pesticide Registration: H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 EPA File Symbol: 69268-E Response to EPA letter of 07-22-98 OPP ID # 233313 07-29-1998

Dear Ms Hasty:

As suggested by Mr. Kish, this letter is directed to you rather than Mr. Swindell as he is away and you are listed as the assigned contact person. In response to that letter of 07-22-98 we are providing the following:

Transmittal letter.

Application for Pesticide Registration Form (OPP ID #233313).

 Copy of the CSF corrected to indicate the proper name of the product and of the as well as the verified pounds per gallon of this product. There are no other changes in the CSF.

Required Certification with Respect to Citation of Data using the new form.

5. Required data matrix using the new forms, since the active ingredient is from an unregistered source.

Copy of letter from Patrick Stewart explaining the origins of the name of the products.

 Three copies of Volume 1 - Product Chemistry - H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 -An Oxidizing Multipurpose, 1-Step Cleaner, Degreaser, Sanitizer (Non-Food Contact Surfaces, Virucide, & Deodorizer for Hard Surfaces - Revised Sections per EPA letter 07-22-98 only, Sections 61-3, and 63-17.

Five copies of the label with the name adjusted to be identical to the name of the product on the CSF.

We have been assured by that they will send the needed data for to you by today at the latest. The toxicology and efficacy MRIDs are either under review or have just had the reviews completed under EPA File Symbol 69268-R. Mr. Tony Kish of your section is the Registration Specialist assigned the product H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112.

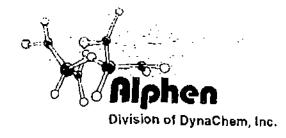
Please let me know directly if you have additional questions regarding this product. This is the second of the peroxide products manufactured by Alphen, Inc., and we have been working with the assistance of Dennis Edwards and Marshall Swindell to get them registered at this time as sanitizers, virucides as well as cleaners. Alphen is a very small company and is very anxious to have the registration of the products finalized by early August so that they can introduce them at the Fall meeting of the National group that sponsors these types of products. Any assistance that you can give us would be greatly appreciated.

I would appreciate it if you would call me as soon as the Agency has completed review of this submission so that I can arrange to pick up the response. Your letter dated the 22nd of July took a week to travel to Frederick and the Sponsor would rather that time be spent on cleaning up any problems.

Thank you for your assistance with this Application.

Sincerely yours,

Kyle H. Sibinovic, Ph.D. Agent for Alphen, Inc.



# Memo

To: Kyle Sibinovic, Ph.D.

From: Patrick Stewart

Date: 07/28/98

H<sub>2</sub>Orange<sub>2</sub> trade name

We "coined this product name in early 1997 and have been using it on our product labels, literature and trade advertising since that time. We have applied for trademark on both the name and the name with our logo. To my knowledge we have never had any comment concerning confusion as a result of the product name.

Thanks

Page 1

#### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

ALPHEN, INC. P.O. BOX 19 GEORGETOWN, IL 61846

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/30/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

#### Rejected study [01] :

\* When data confidentiality is claimed under FIFRA Section 10 (d)(1)(A), (B), or (C), all confidential information must be excised from the body of the study and placed in a Confidential Attachment. See pages 8 and 15 of PR Notice 86-5.

#### SHALDRA, INC. 4327 REELS MILL RD - FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Pam Hasty
Registration Specialist
Antimicrobial Program Division (7510W)
US Environmental Protection Agency
Crystal Mall 2, Room 266A
1921 Jefferson Davis Hwy
Arlington, VA 22202

Re:Application for Pesticide Registration: H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 EPA File Symbol: 69268-E Response to EPA letter of 07-22-98 OPP ID # 233313

Dear Ms Hasty:

As suggested by Mr. Kish, this letter is directed to you rather than Mr. Swindell as he is away and you are listed as the assigned contact person. In response to that letter of 07-22-98 we are providing the following:

07-29-1998

- 1. Transmittal letter.
- 2. Application for Pesticide Registration Form (OPP ID #233313).
- Copy of the CSF corrected to indicate the proper name of the product and of the as well as the verified pounds per gallon of this product. There are no other changes in the CSF.
- 4. Required Certification with Respect to Citation of Data using the new form.
- 5. Required data matrix using the new forms, since the active ingredient is from an unregistered source.
- Copy of letter from Patrick Stewart explaining the origins of the name of the products.
- 7. Three copies of Volume 1 Product Chemistry H<sub>2</sub>Orange<sub>2</sub> Concentrate 117 -An Oxidizing Multipurpose, 1-Step Cleaner, Degreaser, Sanitizer (Non-Food Contact Surfaces, Virucide, & Deodorizer for Hard Surfaces Revised Sections per EPA letter 07-22-98 only, Sections 61-3, and
  - Five copies of the label with the name adjusted to be identical to the name of the product on the CSF.

We have been assured by the latest they will send the needed data for the population of the population of the latest. The toxicology, and efficacy MRIDs are either under review or have just had the reviews completed under EPA File Symbol 69268-R: Mr. Tony Kish of your section is the Registration Specialist assigned the product H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112.

Please let me know directly if you have additional questions regarding this product. This is the second of the peroxide products manufactured by Alphen, Inc., and we have been working with the assistance of Dennis Edwards and Marshall Swindell to get them registered at this time as sanitizers, virucides as well as cleaners. Alphen is a very small company and is very anxious to have the registration of the products finalized by early August so that they can introduce them at the Fall meeting of the National group that sponsors these types of products. Any assistance that you can give us would be greatly appreciated.

I would appreciate it if you would call me as soon as the Agency has completed review of this submission so that I can arrange to pick up the response. Your letter dated the 22nd of July took a week to travel to Frederick and the Sponsor would rather that time be spent on clearing up any problems.

Thank you for your assistance with this Application.

Sincerely yours,
Kykethelberright

Kyle H. Sibinovic, Ph.D. Agent for Alphen, Inc.

\*Inert ingredient information may be entitled to confidential treatment\*

\*Product ingredient source information may be entitled to confidential treatment\*

### CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 6	9268-E	PM 33	ACTION CO	DDE / 7 2
DESCRIPTOR New a	adication p	Du Reget	solion	
[ ] CHILD RESISTA	NT PACKAGING	[ ] NON-	IFICATION RESIDENTIAI APPLICABLE	L USE ONLY
REGISTRATION TYPE	: [ ] COND	TIONAL (	] UNCOND	ETIONAL .
PROPOSED CLASSIFI	CATION: [	GENERAL (	RESTRIC	CTED USE
DATE ON APPLICATI	ON EPA	RECEIVE DATE	PM RI	ECEIVE DATE
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FISH/WILDLIFE				
OTHER				
STATUS				
				<del></del>
RESPONSE CODI	E/	RESPON	SE DATE	UL 2.2 1998

SCIENCE GROUP	DIVISION	BRANCH	SECTION	CSF LABEL Y/N Y/N
CHEMISTRY_	AD	EASSB	CTT	
EFFICACY	AD	EASSB	EET	
ACUTE TOX	AD	EASSB	CTT	
RISK TOX	AD	RASSB	TEAM 1	
EXPOSURE	AD	RASSB	TEAM 1	
ENV. FATE	AD	RASSB	TEAM 2	
Fish/WILD	AD	RASSB	TEAM 2	
		STRUCTIONS		
Please	seview Cho	mestry L	da (	OF X
Label &	los acceptai	belity - m	SOSL	, in cluded
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		STRUCTIONS		
			et je det jegale.	

Attention: Kyle H. Sibinovic, Ph.D. Agent for Alphen

Subject: H2Orange2 Super Concentrate 117 EPA File Symbol No. 69268-E Your Application Dated June 11, 1998

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is unacceptable.

The Confidential Statement of Formula dated April 6, 1998 is in compliance with PR Notice 91-2, it agrees with the label and the CSF would be acceptable when all inert ingredients are verified.

The following information should be provided:

- 1. Your supplier should submit to this Agency, the complete chemical composition of including the chemical name, CAS Reg. No. and the percentage of each component in each product.
- 2. Please note that based on the Confidential Statement of Formula, the label ingredient statement should declare 3.95% of Hydrogen Peroxide.
- 3. Please verify the density or pounds per gallon for this product.
- 4. The label may have only one product name and it must be the same name as in the Confidential Statement of Formula

5. The product nar	ne "H2Orange2	Super Concer	trate 117" is r	nisleading. P	lease clarify	
"H2Orange?" i	n the product nar	meGONCURRENC	:ES	·	·	
SYMBOL 75/0W						
SURNAME CATO						
DATE 100/5		*************	***************************************			
EDA En. (200 (A / Lpo)				<u> </u>	OFFICI	AL FILE COP

A Form 1320-1A (1/90) Printed on Recycled Paper

nert ingredient information may be entitled to confidential treatmen

The submitted product chemistry data in MRID No. 445823-01 for Guideline Ref. No's. 61 and 62 are in compliance with 40 CFR Part 158.155 - 158.180 and the product chemistry data for Guideline Series 63.

- 7. For Guideline Ref. No. 63-17, storage and stability, please submit results of 10 months study.
- 8. Please note that Guideline Ref. No. 61-3 is the discussion of formation of impurities, it is not the discussion of an active ingredient.
- Please note that you do not qualify for the Formulator's Exemption because you are using an unregistered source of active ingredient.
- 10. Please note that your Certification with Respect to Citation of Data form is incorrect, option 2 is not applicable since Hydrogen Peroxide is not a new chemical or has exclusive data rights. Also note that under option 3 you neglected to choose a method of support (i.e., Cite-All or Selective).
- 11. Please indicate if the identified toxicology and efficacy MRIDs have been reviewed and under which registration number they were submitted.

The Agency reserves a full label review until the abovementioned deficiencies are addressed.

This letter does not constitute registration and the product may not be lawfully marketed until the required information has been submitted for review and found acceptable.

If you have any questions concerning this letter, please contact Pam Hasty at (703) 308-7933.

Sincerely,

Marshall Swindell

Product Manager 33

Regulatory Management Branch I Antimicrobial Division (7510W)

445823-00

SHALDRA, INC. 4327 REELS MILL RD FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Marshall Swindell Product Manager 33 Antimicrobial Program Division (7510W) US Environmental Protection Agency Crystal Mall 2, Room 265A 1921 Jefferson Davis Hwy Arlington, VA 22202

Re-Application for Pesticide Registration: H₂OR/ANGE₂ SUPER CONCENTRATE 117 EPA File Symbol: 69268- E OPP ID # 233327 ⊕6-11-1998

Dear Mr. Swindelly

Enclosed please find the following information for the above referenced product:

- 1. Transmitta! letter.
- 2. Application for Pesticide Registration OPP ID # 233327.
- Administrative information including the CSF, Formulators exemption, Certification with Respect to the Citation
  of Data, and Matrix.
- Three (3) copies of the following:

Volume: 1 - Study Title: Product Chemistry - H₂Oange₂ Super Concentrate 117 - An oxidizing
4.4.5.8.2.3.0.1 multipurpose, 1-step deaner, degreaser, sanitizer (non-food contact surfaces, virucide & deoidorizer for hare surfaces, (Alphen 98-PC-02)

Five (5) copies of the Proposed Master Label.

This is the second of a series of products that Alphen, Inc., has marketed as cleaners/degreasers for a number of years. Testing submitted with their product H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112 (EPA File Symbol 69268-R) is to be used in the evaluation of this product as well as the use dilution for this product results in the same concentrations of active ingredients. It is the aim of the sponsor to have each product registered as non-food contact surface sanitizers, and virucides as well.

The reference MRID #S for this submission that were assigned to the first product, EPA File Symbol 69268-R are:

44532001 - Product Chemistry 44532002 - AOAC Sanitizer Test Report

44532003 - HIV Virucidal Test Report 44532004 - Hydrogen peroxide OEL Criteria Document

44560101 - Virucidal Effectiveness Test Report

The products use hydrogen peroxide as the active ingredient and as a part of the initial submission, the Sponsor included the ECETOC Special Report No. 10 on hydrogen peroxide in place of the acute toxicology and other pertinent information to assist in the registration process for this product. The associated MRID# is as given above.

The Sponsor hopes that the problems encountered with the first submission have now been solved and that both submissions will be considered for rapid approval of their Applications for Pesticide Registration.

tif you have questions, please contact me at the above numbers. Thank you for your assistance with this Application.

Sincerely yours, Kee Let Liberry 140

Kyle H. Sibinovic, Ph.D.

Agent for Alphen, Inc.

#### U.S. ENVIRONMENTAL PROTECTION AGENCY Office of Pesticide Programs

ALPHEN, INC. C/O SHALDRA, INC. 4327 REELS MILL RD FREDERICK, MD 217047759

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 06/15/98. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

445823-00

SHALDRA, INC. 4327 REELS MILL RD FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Marshall Swindell
Product Manager 33
Antimicrobial Program Division (7510W)
US Environmental Protection Agency
Crystal Mall 2, Room 266A
1921 Jefferson Davis Hwy
Arlington, VA 22202

Re:Application for Pesticide Registration: H₂OR/NGE₂ SUPER CONCENTRATE 117 EPA File Symbol: 69268- E

OPP ID # 233327 06-11-1998

Dear Mr. Swindall:

Enclosed please find the following information for the above referenced product:

- Transmittal letter.
- Application for Pesticide Registration OPP ID # 233327.
- Administrative information including the CSF, Formulators exemption, Certification with Respect to the Citation
  of Data, and Matrix.
- 4. Three (3) copies of the following:

Volume 1 - Study Title: Product Chemistry - H<sub>2</sub>Oange<sub>2</sub> Super Concentrate 117 - An oxidizing 458230 1 multipurpose, 1-step cleaner, degreaser, sanitizer (non-food contact surfaces, virucide & deodorizer for hard surfaces. (Alphen 98-PC-02)

Five (5) copies of the Proposed Master Label.

This is the second of a series of products that Alphen, Inc, has marketed as cleaners/degreasers for a number of years. Testing submitted with their product H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112 (EPA File Symbol 69268-R) is to be used in the evaluation of this product as well as the use dilution for this product results in the same concentrations of active ingredients. It is the aim of the sponsor to have each product registered as non-food contact surface sanitizers, and virucides as well.

The reference MRID #S for this submission that were assigned to the first product, EPA File Symbol 69268-R are:

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44532003 - HIV Virucidal Test Report 44532004 - Hydrogen peroxide OEL Criteria Document

44560101 - Virucidal Effectiveness Test Report

The products use hydrogen peroxide as the active ingredient and as a part of the initial submission, the Sponsor included the ECETOC Special Report No. 10 on hydrogen peroxide in place of the acute toxicology and other pertinent information to assist in the registration process for this product. The associated MRID# is as given above.

The Sponsor hopes that the problems encountered with the first submission have now been solved and that both submissions will be considered for rapid approval of their Applications for Pesticide Registration.

lif you have questions, please contact me at the above numbers. Thank you for your assistance with this Application.

Sincerely yours, Kale Sharing & D

Kyle H. Sibinovic, Ph.D. Agent for Alphen, Inc.

SUBJECT: PRODUCT CHEMISTRY REVIEW - Antimicrobials Division

DP Barcode <u>D247515</u> Reg. No. or File Symbol <u>69268-</u>

Manufacturing-Use [ ] OR End-Use Product [ ]

TO: Marshall Swindell / Pamela Hasty

FROM: Anna Skapars, Chemist

Efficacy and Science Support Branch

THRU: Michelle Wingfield, Acting Chief Efficacy and Science Support Branch

#### SUMMARY OF INFORMATION REVIEWED AND FINDINGS

This application is for registration of a new product.

- Confidential Statement of Formula dated 4-6-98 is in compliance with PR Notice 91-2 it agrees with the label and CSF would be acceptable when all wint ingledunts are verified.
- B. Ask your supplie to submit to this Agency complete chemical composition of in checking chimical mame, CAS Rig. No. and percentage of each component in each product.
- C. Please note That based on Confidential Statement of Formula the label ingreduct statement should declare 3.95% of Hydrogen Peroxide.
- Please verify the density or founds que gallon for this product.
  - E. Label may have only one product name and it must be The same name as in Confidential Statement of Formula.
  - I Product name "Ha Orange a Super Concentrate 117" is mishading Please clarify "Ha Orange a" in the product name.
  - G. Sulmitted product chemistry date in MRID No. 445823-01
    for Buiddin Ref. No's 61 and 62 are in compliance
    With 40 CFR part 158.155-158.180 and product chimistry
    date matrix for Suideline Series 63
  - H. For Suideline Ref. No. 63-17 storage and stability please submit results of 10 months steedy.
- 6. Please note that Suiddine Ref. No. 61-3 is discussion of 7 17 formation of impurition, it is not discussion of anna shopers ingredient.

# PRODUCT CHEMISTRY REVIEW

# END-USE PRODUCT [/] MANUFACTURING-USE PRODUCT [ ] EPA Reg. No. (or Pile Symbol No.) 69268-E

Reg	gistration [/]		Reregistration [ ]
DΡ	D247515 Barcode/Chemist: Anna S	Kapars	Case No.:
1)		3)	
2)		4)	
1.	Product Name: Hy Drange,	, Super Concent	eate 117
2.	Company:		
3.	Type of Submission: New [ "ME-TOO" [ ] Alte Expt Use Permit [ ] Ot	ernate Formulation	[ ] REPACK [ ]
4.	CONFIDENTIAL STATEMENT OF	P PORNULA	· · · · · · · · · · · · · · · · · · ·
. •	4a. Type of formulation	and source regis	tration
	<ul> <li>Non-integrated for Are all TGAI</li> </ul>		[ ] · yes [ ] · no [ ]
	<ul> <li>Integrated formul</li> </ul>	ation system	· M
	<ul> <li>If "ME-TOO", spec product:</li> </ul>	ify EPA Reg. No.	of existing
- "	4b. Clearance of inerts Cleared for food us - yes [ ] - no [ ]. Cleared for non-foo		.1001: } % d[] * e[]
•		:	
	4c. Physical state of p	roduct: Liqui	L
	4d. The chemical IDs, a that for the TGAIs) consistent with tha	, density, pH, an t given in GRN 61	d flammability are

-	
4e.	Density (or bulk density for solids): at .c. 8.33 lbs/gall
4f.	pH (if dissolved or dispersed in water): 36
4g.	Flash point and/or flame extension: $> 150^{\circ}F$
4h.	NCs and CLs are acceptable: • [ 1 • not acceptable [ ]
4i.	Active ingredient(s) NC LCL UCL
Ì.,	A. Hydrogen Peroxide 3.95% 3.83% 4.07%
	в.
-	<b>c.</b>
	D.
4j.	For products produced by an integrated formulation system:
	<ul> <li>All impurities of toxicological significance have an UCL:</li></ul>
	<ul> <li>All impurities ≥ 0.1% in the product have been identified: yes [] • no [] • not applicable [</li> </ul>
RODU	CT LABEL
5 <b>a</b> .	The active ingredients statement (chemical IDs and NCs) is consistent with the CSF: • yes [ 1 • no [ ]
5b.	The formulation contains one of the following: • 10% or more of a petroleum
	distillate: • yes [] • no [/] • 1% or more of methyl alcohol: • yes [] • no [/]
	<ul> <li>sodium nitrite at any level: - yes [] · no [/]</li> <li>a toxic List l inert at any level: · yes [] · no [/]</li> <li>arsenic in any form: · yes [] · no [/]</li> </ul>
5c.	If yes to any of the above, does the inert ingredients statement contains a footnote indicating this? • yes [ ] • no [ ] • not applicable [/]
5 <b>d</b> .	The appropriate warning statement regarding flammability or explosive characteristics of the product are given on the label: • yes [/] • no [] • not applicable []
	244 - 244 - 244 - 244 - 244 - 244 - 244 - 244 - 244 - 244 - 244 - 244 - 244 - 244 - 244 - 244 - 244 - 244 - 24

- 5e. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:

   yes [ ]
   no [ ]
- 6f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information):

  yes []
  no [/]

# 6. PRODUCT CHEMISTRY (GRN 61, 62, 63)

6a. Chemical IDs/Manufacture/Analytical/ Information	Accept of Information	MRID No.
61-1 Chemical ID (see Appendix)	A	445823-01
61-2a Manufacturing Process2	A	445823 -01
61-2b Formulation Method <sup>3</sup>	A	445823 - 01
61-3 Discussion of Impurities		
62-1 Analysis <sup>5</sup>	A	445823-01
62-2 Certified Limits <sup>6</sup>	A	CSF
62-3 Analytical Method for Als7	А	445825-01

aft leg. NO. 69268-2
Page is not included in this copy.  Pages $249$ through $250$ are not included in this copy.
The material not included contains the following type of information:
Identity of product inert ingredients.
Identity of product impurities.
Description of the product manufacturing process.
Description of quality control procedures.
Identity of the source of product ingredients.
Sales or other commercial/financial information.
A draft product label.
The product confidential statement of formula.
Information about a pending registration action.
L FIFRA registration data.
The document is a duplicate of page(s)
The document is not responsive to the request.
Internal deliberative information.
Attorney-Client work product.
Claimed Confidential by submitter upon submission to the Agency.
The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

(logo)

# H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD SURFACES

ACTIVE INGREDIENTS

Hydrogen peroxide

3.98%

OTHER INGREDIENTS

96.02%

TOTAL

100.00 %

# KEEP OUT OF REACH OF CHILDREN

# **CAUTION**

### PRECAUTIONARY STATEMENTS

SEE LEFT LABEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 069268-E
EPA Est. No. 069268-IL-001

ALPHEN, INC. MAPLE GROVE ROAD GEORGETOWN, IL 61846

NET CONTENTS: 1 gallon

**NET WEIGHT:** 

This product is not to be used as a terminal sterifant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mulcous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

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# PRECAUTIONARY STATEMENTS

# CAUTION HAZARDS TO HUMAN AND DOMESTIC ANIMALS KEEP OUT OF REACH OF CHILDREN

# STATEMENT OF PRACTICAL TREATMENT

In case of CONTACT, Concentrate causes moderate eye irritation, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician if irritation persists. Remove and wash contaminated clothing before reuse. Product, after dilution according to directions, is non-irritating. If SWALLOWED, Drink promptly large quantity water. Call a physician immediately, if large amount ingested.

**Caution.** Concentrate may cause eye irritation. Do not get in eyes. Wear safety glasses or other eye protection when handling. Avoid contamination of food. Wash thoroughly after handling. (After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required.)

IN CASE OF SPILL: Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE**: Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by disposal. Wastes fresulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL**: Completely empty container. Do not reuse empty containers. Leave plastic bag in original box discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.

#### DIRECTIONS FOR USE

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

Alphen 117, when used as directed as a sanitizer, kills 99.99% or more of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruinosa, Streptococcus faecalis, and Escherichia coli. When used as directed as a virucide, Alphen 117 kills the following viruses in 5 minutes at room temperature (20+/-1°C): Herpes 2 and Influenza A\_Japan. HIV-1 (Human Immunodeficiency Virus), is killed at a concentration of 1 oz per gallon (1 part of product plus 127 parts of water) in 5 minutes at room temperature. However, to insure that all bacterial and viral agents are killed as stated, the higher concentration of active (10 oz/gallon) should be used.

To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces: Add 10 ounces of this product per gallon of deionized water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution, then, treated for sanitizer or virucidal effect.

To use as a sanitizer and virucide in bathrooms: Use above procedure on sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stalls and floors where urine and soils build up.

<u>HIV-1</u>: Kills HIV-1 (Humen immunodeficiency viurs) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of Alphen 117 to 127 parts of water), in 5 minutes at room temperature (20 - 25 C) in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1) (Associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned form surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution. Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label. Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officier.



#### **CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute manually with satellite measuring bottle)

LIGHT DUTY (1 Oz / gallon ) GREEN
Streak free window, mirror and stainless steel cleaning
General floor cleaner for mopping & auto scrubbers
Bonnet cleaning solution for carpets
Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gallon ) BLUE
General wipe down cleaner
Mopping solution for Bathroom and Kitchen floors
General carpet spot remover

HEAVY DUTY (10 Oz / gallon ) RED
Bathroom, shower room, tile & grout cleaner
Urine and garbage odor eliminator
Pre-spray for carpet extraction
General degreaser
Heavy soil wipe down cleaner
Heavy carpet spot remover
Cleans Mold & mildew

SUPER DUTY (24-48 Oz / gallon) PURPLE Renovation of tile & grout surfaces Difficult urine & garbage odor destruction Scuff marks and stubborn stains Cleans heavy mold & mildew

1-Step Cleaning and Sanitizing: Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution.

### Deodorizing

For general deodorizing, use 2 part Alphen 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts Alphen 117 to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-ileostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.



# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

06/16/98

OFFICE OF PREVENTION. PESTICIDES AND TOXIC SUBSTANCES

Shaldra, Inc. 4327 Reels Mill Road Frederick, MD 21704-7759

PRODUCT NAME: H2 Orange Super Concentrate 117

COMPANY NAME: Shaldra, Inc.

**OPP IDENTIFICATION NUMBER: 233327** 

EPA FILE SYMBOL: 69268-E EPA RECEIPT DATE: 06/11/98

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

### DEAR REGISTRANT.

The office of Pesticides Programs has received your application for a new registration and it passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions, please contact Marshall Swindell, Product Manager 33 at (703)-308-6341.

Sincerely,

Front End Processing Staff

Information Resources & Services Division

Information Services Branch

### SHALDRA, INC. 4327 REELS MILL RD FREDERICK, MD 21704-7759 (301) 695-1200 FAX: (301) 695-1409

Marshall Swindell Product Manager 33 Antimicrobial Program Division (7510W) US Environmental Protection Agency Crystal Mail 2, Room 266A 1921 Jefferson Davis Hwy Arlington, VA 22202

Re:Application for Pesticide Registration: H<sub>2</sub>ORANGE<sub>2</sub> SUPER CONCENTRATE 117 EPA File Symbol: 69268- E
OPP ID # 233327
06-11-1998

Dear Mr. Swindell:

Enclosed please find the following information for the above referenced product:

- Transmittal letter.
- Application for Pesticide Registration OPP iD # 233327.
- Administrative information including the CSF, Formulators exemption, Certification with Respect to the Citation of Data, and Matrix.
- 4. Three (3) copies of the following:
  - Volume 1 Study Title: Product Chemistry H<sub>2</sub>Oange<sub>2</sub> Super Concentrate 117 An oxidizing multipurpose, 1-step cleaner, degreaser, sanitizer (non-food contact surfaces, virucide & deodorizer for hard surfaces. (Alphen 98-PC-02)
- 5. Five (5) copies of the Proposed Master Label.

This is the second of a series of products that Alphen, Inc, has marketed as cleaners/degreasers for a number of years. Testing submitted with their product H<sub>2</sub>Orange<sub>2</sub> Super Concentrate 112 (EPA File Symbol 69268-R) is to be used in the evaluation of this product as well as the use dilution for this product results in the same concentrations of active ingredients. It is the aim of the sponsor to have each product registered as non-food contact surface sanitizers, and virucides as well.

The reference MRID #S for this submission that were assigned to the first product, EPA File Symbol 69268-R are:

44532001 - Product Chemistry 44532002 - AOAC Sanitizer Test Report 44532003 - HIV Virucidal Test Report 44532004 - Hydrogen peroxide OEL Criteria Document

44560101 - Virucidal Effectiveness Test Report

The products use hydrogen peroxide as the active ingredient and as a part of the initial submission, the Sponsor included the ECETOC Special Report No. 10 on hydrogen peroxide in place of the acute toxicology and other pertinent information to assist in the registration process for this product. The associated MRID# is as given above.

The Sponsor hopes that the problems encountered with the first submission have now been solved and that both submissions will be considered for rapid approval of their Applications for Pesticide Registration.

tif you have questions, please contact me at the above numbers. Thank you for your assistance with this Application.

Sincerely yours, Keelet Library M. D.

Kyle H. Sibinovic, Ph.D. Agent for Alphen, Inc.

IFT lease read instructions on reverse before completing form:	Form Approve	1. OMB No. 2070-0060	Approval expires 2-28-
SEPA Environmental Protection Age Weshington, DC 20460	ncy.	Registration Amendment Other	OPP Identifier Number
Application for F	Pesticide - Section		Action to the second
Company/Product Number 69268-E	2 EPA Product Managers W 058 hall	Swindell 3. Pro	posed Classification
Company/Product (Name) Ho Orango I Super Concentrate 177	PM/ 33		None Restricted
Name and Address of Applicant Include ZIP Code  Alphan Inc  Maple Grove Rd Box 19  George John Include Sip Check if this is a now address	6. Expedited Review. (b)(i), my product is sin to: EPA Reg: No:	nilar or identical in co	nposition and labeling
Sec	tion Ell 👉 🐃 🗈		
Amendment - Explain below.  Resubmission in response to Agency letter dated  Notification - Explain below.	Final printed labs Agency letter da - "Me Too" Applic Other - Explain b	ted ation.	
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Typed Name  Kyle H. S. Binovic PhD	٦ ٩-١١ - ما ٥	151	
A Form 8570-1 (Rev. 8-94) Previous editions are obsolete:	White · E	PA File Copy (original)	Yellow Applicant Co

# PAPERWORK-REDUCTION ACT NOTICE and INSTRUCTIONS

PAPERWORK REDUCTION ACT NOTICE: Public reporting burden for this collection of information is assignated to everage 0.85 hour par response, including time for reviewing instructions, soorching existing data sources, gethering and mountaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other espect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2138), U.S. Environmental Protection Agency, 40 1. M. Street, SW. Washington, DC 20460; and to the Office of Information and Regulatory Affairs Office of Management and Budget, Washington, DC 20503

INSTRUCTIONS: This form is to be used for all applications for new regletration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc...in order to process en application for a new registration submitted on this form, the following meterial must accompany the application: 10 m 15 m

- 1. Contribution with Respect to Citation of Data (EPA Form 8570-29): [If not exempted by 40 CFR 152.81 (b) (4)]
- 2. Confidential Statement of Formula (EPA Form 8570-4);
- Formulator's Exemption Statement (EPA Form 8570-27);
- Five copies of draft labeling:
- 5. Three copies of any data submitted; a say
- Authorization letter where applicable;
- 37 Matrices where applicable.

Submission of Labeling : Labeling should first be submitted in the form of distribute with all applications for new registration. Such draft labels may be in the form of typed lebel text on 8.5 x 11 inch paper for submission or a mockup of the proposed lebel. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on x 11 inch paper for submission."

Submission of Date Date submitted in support of this application must be submitted in accordance with PR Notice 86-5.

SPECIFIC INSTRUCTIONS: Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A. for which you are submitting this application. For applications submitted in connection with New Registration actions. Sections , III, and IV must be completed by the applicant. For applications cubmitted to connection, with amended recognitions cubmits sink, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant. Block A. Chock the appropriate action for which you are submitting this form

SECTION I - This section must be completed, as applicable tor all registration actions:

- Company/Product Number Insert your Company Number; if one has been assigned by EPA. This number may have been assigned to you as a basic registered; insert the Product Number.
- EPA Product Manager If known, fill in the name and PM number of the EPA Product Manager.

  Proposed Classification Specify the proposed classification of this product.

1-48 / 4- 3 m

- Product Name Enter the complete product name of this posticide estit will appear on the level. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
- Name and Address of Applicant -The name of the firm or person and address shown in your application is the person of firm to whom the registration will be issued. If you are ecting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an outhorized agent residing in the United States to act for them in all, registration matters. The name and complete mailing address of such an agent must accompany this application.
- Expedited Review. FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registration that ere similar or identical to other pasticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you bulleve is similar to or identical to your product. The product must be similar or identical in both formulation, and labeled uses.

SECTION II . This section must be completed for all applications submitted to amend the registration only of a currently registered product: (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that partains to a specific EPA-registered product. This saction is not to be used for a new application for registration.

1. Subject of submission. Check the applicable block and provide the Agency latter date if appropriate. Provide a brief explanation of the purposets for the submission, such as the addition of a site, pestor crop (specify); amend the Confidential Statement of Formula by.... Faregistration submission": "general label revision of use directions." Attach a separate page if additional space is needed.

SECTION III (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments: Torre

- 1. Type of Packaging Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
- Type of Retail Confiner Indicate type of container in which product will be marketed
- 3. Lecalibn of Net Contents Indicate the location of the net contents information for your product.
- 4. Sizolaf of Retal Container Specify the net contents of all retail containers for your product.
- 5. Education of Use Directions Indicate the location of the use directions for your product.
- 8. Menner in which lakel is affixed to product Indicated the method product label is attached to retail container.

SECTION IV (Castact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration. esubmission, "me-too," reregistration, etc.

- 3-5. Self-explanatory.



United States Environmental Protection Agency
Washington, DC 20460

# Formulator's Exemption Statement

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(3) Indicate by checking (A) or (B)  (A) An accurate Confidential St attached to this statement. The	atement of Formula (E at formula statement in	<i>PA Form 8570-4</i> ndicate, by comp	any name, registra		# - - -
ingredient in the manufacturing, for ingredient, which is registered und for at least each use for which my	ormulation or repackag der FIFRA Section 3, is	ing of another property	oduct which conta	ins that active	
(2) Of these, each active ingredie	ent listed in paragraph	(4) is present so	lely as the result of	f the use of that a	ctive
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# Paperwork Reduction Act Notice

The public reporting barden for this collection of information is estimated to average 1.5.3 hours per response, including familiarization with the form, organizing the necessary information, and completing the form. Send any comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Chief, Information Policy Branch, PM-223 U.S. Environmental Protection Agelicy 401 M Street, S.W., Washington, DC 20460

and to

Office of Management and Budget Paperwork Reduction Project (2070-0060) Washington, DC 20503

United States

Form Approved

<b>WEPA</b>	Environmental Protection Agency OMB No. 2070-0000, Washington, DC 20460 Approval Expires 02-28
-	Certification with Respect to Citation of Data : - 3 3 3 3 3 3
Applicants Name and	
ADIVIBI	on of Dynachan Product Name H2 Orange 2 Super Concentrate
·	Data of Application 06-11-98
for the san Forni 8570  1. This applied indicate product submitted boxes, i  2. I certify	plication is supported by all data submitted or cited in the application. In addition, if cite-all options are ad, this application is supported by all data in the Agency's files that concern the properties or effects of this that is identical or substantially similar and that is one of the types of data that would be required to be ed if this application sought the initial registration of a product of identical or similar composition, and d uses under the data requirements in effect on the date of approval of this application. (Check the appropriate in items 2 and 3, or 4 below that periain to your application.)  that, for each study cited in support of this application for registration that is an exclusive use study.  I am the original submitter*; or  I have obtained the written permission of the original submitter for the companies who are original data submitters (insert names of companies)  with the appropriate chemical name) to cite that study*  that, for each study cited in support of this application for registration that is not an exclusive use study:
	am the original data submitter*; or  have obtained the written permission of the original data submitter for
	(for, multiple chemicals link the companies who are original data submitters (insert names of companies) with the appropriate chemical name) to cite that study*; or
h ii F	have notified in writing the companies land the for have general land that insert name of companies) (insert name of chemical) (insert name of chemi
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	hemicals link the companies who are original data submitters with the appropriate chemical name).  at have submitted the studies which I have cited (Selective method*).
4.     I	certify that for each study cited in support of this application I am not required to offer data compensation or obtain written permission because all time periods for exclusive-use and data compensation have expired.

\* A Data Matrix identifying these studies is attached. (Note: a Data Matrix is not required under the cite-all method)

PhD - Agen Date Name and Title Kyle H. SIBINOUIL

General Offer to Pay: I hereby offer and agree to pay compensation to other persons, with regard to the approval of this application, to the extent required.

Name and Title Date 06-11-98

Signatura

### Paperwork Reduction Act Notice:

The public reporting burden for this collection of information is estimated to average 2.5 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining needed data, and completing and reviewing this application form. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: Chief, Information Policy. Branch, 2136, U.S. Environmental Protection Agency, 401 M Street, S. W. Washington, DC 20460; and to Office of Management and Budget, Paperwork Reduction Project (2070-0055); Washington, DC 20503; marked "Attention Desk Officer for EPA."

# DATA REQUIREMENT LISTING FOR THE OWNER SUBMISSION METHOD OF SUPPORT

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\$158.20	PRODUCT CHEMISTRY	<u> </u>		<u>.</u>	<u> </u>	ļ <u>-</u>			$\perp \downarrow \downarrow$	$\perp$	$\bot$
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61-2	_Statement of composition	\ \									
61-3	Discussion of formation of ingredients	1 4		:							
62-1	Preliminary analysis	Ty:					1				
62-2	Certification of limits	Y							$\prod$		
62-3	Analytical methods for enforcement limits	Ty		<del></del>			:				
63~2	Color	1 4		······································							
63-3 :	Physical stage:	Y		<del></del>							
63-4	Odor	Y			<u> </u>						
63-5	: Melting :point	NA									
63-6	Rolling point	NA		······································							
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egulation art 158/ wideline umber	8b.	9a. Submitted	9b. Date Submitted	9c. Submitted by another person/firm (name)	9d. Permission Letter	9e. Public	9f. Other (Explain)	EP/ NUR EP/	a ac Mber	Cess Or Enti	OTHE	ÉR
158.20	PRODUCT CHEMISTRY (Continued									$\prod$		
63-8	Solubility	NA								$\perp \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \! \!$		
63-9	Vapor pressure	NA										L
63-10	Dissociation constant	NA								$\prod$		
63- <u>11</u>	Octanol/water partition	NA							$\prod$	$\prod$		
63~12	pH	Y	06-11-98						$\prod$	$\prod$		
63-13	Stability	NA.								$\coprod$		
63-14	Oxidizing/reducing reaction	NA							Ш			L
63-15	Flammability	У	06-11-98									
63-16	Explodebility	У	<b>{</b>							$\coprod$		
63-17	Storage stability	17 40	<b>√</b>						Ш	Ш		
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63-19	Miscibility	ろの							IT	H		

# DATA REQUIREMENT LISTING FOR THE OWNER SUBMISSION SETHOD OF SUPPORT

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# H<sub>2</sub>ORANGE<sub>2</sub> CONCENTRATE 117

OXIDIZING MULTI PURPOSE 1-STEP CLEANER, DEGREASER & SANITIZER (NON-FOOD CONTACT SURFACES), VIRUCIDE & DEODORIZER FOR HARD SURFACES

**ACTIVE INGREDIENTS** 

Hydrogen peroxide

3.98%

OTHER INGREDIENTS

96.02%

TOTAL

100.00 %

KEEP OUT OF REACH OF CHILDREN

# CAUTION

# PRECAUTIONARY STATEMENTS

SEE LEFT LABEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA Reg. No. 069268-EPA Est. No. 069268-IL-001

ALPHEN, INC. MAPLE GROVE ROAD GEORGETOWN, IL 61846

**NET CONTENTS: 1 gallon** 

NET WEIGHT:

This product is not to be used as a terminal sterilant/disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes, but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disistance.

## PRECAUTIONARY STATEMENTS

# CAUTION HAZARDS TO HUMAN AND DOMESTIC ANIMALS KEEP OUT OF REACH OF CHILDREN

### STATEMENT OF PRACTICAL TREATMENT

In case of CONTACT, Concentrate causes moderate eye irritation, immediately flush eyes or skin with plenty of water for at least 15 minutes. For eyes, call a physician if irritation persists. Remove and wash contaminated clothing before reuse. Product, after dilution according to directions, is non-irritating. If SWALLOWED, Drink promptly large quantity water. Call a physician immediately, if large amount ingested.

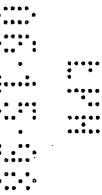
**Caution**. Concentrate may cause eye irritation. Do not get in eyes. Wear safety glasses or other eye protection when handling. Avoid contamination of food. Wash thoroughly after handling. (After product is diluted in accordance with directions for use, safety glasses or other eye protection are not required.)

IN CASE OF SPILL: Clean up immediately. Place leaking container in well ventilated area. To clean up spill, flush area with large quantity of water. Avoid run-off into storm sewers and ditches leading to natural waterways.

**STORAGE**: Do not contaminate water, food, and or feed by storage. Avoid freezing conditions. Avoid high temperatures. Do not exceed storage temperatures of 95°F. Best storage temperatures are between 35°F and 85°F. Overheating in storage may result in increased degradation of product, which will decrease product effectiveness. Keep concentrate away from incompatible materials.

**PESTICIDE DISPOSAL**: Do not contaminate water, food or feed by disposal. Wastes fresulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER DISPOSAL**: Completely empty container. Do not reuse empty containers. Leave plastic bag in original box discard in trash, sanitary landfill or by incineration, or if allowed by State and Local Authorities, by burning. If burned stay out of smoke.



#### **DIRECTIONS FOR USE**

It is violation of Federal law to use this product in a manner inconsistent with its labeling.

Alphen 117, when used as directed as a sanitizer, kills 99.99% or more of the following: Staphylococcus aureus, Salmonella choleraesuis, Klebsiella pneumoniae, Pseudomonas aeruinosa, Streptococcus faecalis, and Escherichia coli. When used as directed as a virucide, Alphen 117 kills the following viruses in 5 minutes at room temperature (20+/-1°C): Herpes 2 and Influenza A<sub>z</sub>Japan. HIV-1 (Human Immunodeficiency Virus), is killed at a concentration of 1 oz per gallon (1 part of product plus 127 parts of water) in 5 minutes at room temperature. However, to insure that all bacterial and viral agents are killed as stated, the higher concentration of active (10 oz/gallon) should be used.

To use as a sanitizer and virucide on inanimate, hard, non-porous surfaces: Add 10 ounces of this product per gallon of deionized water. Apply solution liberally to pre-cleaned hard surfaces, with a spray bottle, pump up pressure sprayer, cloth, sponge or mop. Allow surface to remain wet for 5 minutes, then, either allow to air dry or wipe dry to remove excess liquid. Heavily soiled surfaces should be pre-cleaned with the same solution, then, treated for sanitizer or virucidal effect.

To use as a sanitizer and virucide in bathrooms: Use above procedure on sinks, faucets, counters, urinals, toilets and all hand contact surfaces as well as walls, stells and floors where urine and soils build up.

<u>HIV-1</u>: Kills HIV-1 (Human immunodeficiency viurs) on precleaned environmental surfaces/objects previously soiled with blood/body fluids at a concentration of 1 oz / gallon (1 part of Alphen 117 to 127 parts of water), in 5 minutes at room temperature (20 - 25°C) in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surface/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type I (HIV-1) (Associated with AIDS).

SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION AGAINST HIV-1 (HUMAN IMMUNODEFICIENCY VIRUS OR AIDS VIRUS) OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS: Personal Protection: Wear appropriate barrier protection such as latex gloves, gowns, masks or eye coverings. Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned form surfaces and objects before application of diluted product using the Heavy or Super Duty Cleaning Solution. Contact time: While the HIV-1 virus is inactivated in 5 minutes, at use concentration of 1 oz / gallon, with both organic load and when diluted in hard water (up to 400 ppm hardness), use the recommended contact time for sanitization and virucidal activity as given on this label. Infectious Materials Disposal: Cleaning materials that may contain blood and other body fluids should be disposed of by autoclaving or as directed by the facility safety officier.



#### **CLEANING SOLUTION DILUTIONS & APPLICATIONS**

(Dilute manually with satellite measuring bottle)

LIGHT DUTY (1 Oz / galion ) GREEN

Streak free window, mirror and stainless steel cleaning General floor cleaner for mopping & auto scrubbers Bonnet cleaning solution for carpets Light wipe down cleaner

GENERAL PURPOSE (2 Oz / gallon ) BLUE

General wipe down cleaner
Mopping solution for Bathroom and Kitchen floors
General carpet spot remover

HEAVY DUTY (10 Oz / gallon ) RED Bathroom, shower room, tile & grout cleaner Urine and garbage odor eliminator Pre-spray for carpet extraction General degreaser Heavy soil wipe down cleaner

Heavy carpet spot remover Cleans Mold & mildew

Cleans heavy mold & mildew

SUPER DUTY (24-48 Oz / gallon) PURPLE Renovation of tile & grout surfaces Difficult urine & garbage odor destruction Scuff marks and stubborn stains

1-Step Cleaning and Sanitizing: Using the appropriate cleaning solution for the type of surface to be treated, thoroughly clean the surface, allow to air dry. If needed use additional solution.

#### Deodorizing

For general deodorizing, use 2 part Alphen 117 to 126 parts water (2 oz / gallon). Apply to hard, non-porous surfaces to eliminate generally offensive odors. For effective, high level, deodorizing, use 10 parts Alphen 117 to 118 (10 oz / gallon) parts water. Apply to hard, non-porous surface thoroughly to eliminate odors due to spillage from post-colostomy, post-leostomy dressing and bag changes, and other spills such as urine or fecal matter; smoke or soot deposits, industrial plant processes, mildew and mold, and surfaces in musty closets.

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